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Kalthoff et al.

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For: SECURE NETWORK GATEWAY FOR ACCESSIBLE PATIENT DATA AND
TRANSPLANT DONOR DATA

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Third Party Submission Under 37 C.F.R. § 1.99

Pursuant to 37 C.F.R. § 1.99, the following publications are being submitted for
consideration in connection with the above-identified patent application publication, published
on May 12, 2005:

U.S. Patents and Patent Application Publications:

	<u>Applicant/Patentee</u>	<u>Patent or App. No.</u>	<u>Date of Publication/Issue Date</u>
1)	Perry et al.	5,241,466	August 31, 1993
2)	Evans	5,924,074	July 13, 1999
3)	Cusack et al.	6,493,724	December 10, 2002
4)	Fletcher-Haynes et al.	2001/0034614	October 25, 2001

Other Publications:

5) American Management Systems, Inc., UNOS Vitalink Business System Concept,
November 30, 1993.

6) United Network for Organ Sharing, UNOS Vitalink Pilot Overview and Training Guide,
February, 1994.

7) American Management Systems, Inc., UNOS Organ Information Service Design
Document, September 23, 1994.

07/14/2005 SSITHIB1 00000037 10813918

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- 8) Hutson, Charles J., XPEDITE Organ Information Service - System Analysis and Design Project, April 24, 1995.
- 9) United Network for Organ Sharing, UNet User's Manual – Placement Section, November 21, 2001.
- 10) Dickinson DM, Ellison MD, Webb RL. 2002 SRTR Report on the State of Transplantation: Data Sources and Structure. American Journal of Transplantation 3 (Suppl. 4):13-28, 2003.

In accordance with 37 C.F.R. § 1.99, and 37 C.F.R. § 1.248, a copy of this submission is being served upon the attorneys for the applicant for the above-identified application.

In regard to the filing fee set forth in § 1.17, a check in the amount of \$180.00 is being filed herewith as payment.

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on the date shown below:

this 12th day of July 2005.



CERTIFICATE OF SERVICE

I hereby certify that a copy of this Third Party Submission under 37 C.F.R. § 1.99 was sent via first class mail, postage prepaid to Applicant's counsel:

Taft Stettinius & Hollister LLP
Suite 1800
425 Walnut Street
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this 12th day of July, 2005.



United States Patent [19]

Perry et al.

US005241466A

[11] Patent Number: 5,241,466

[45] Date of Patent: Aug. 31, 1993

[54] SYSTEM FOR ADMINISTERING A CENTRAL DEPOSITORY FOR LIVING WILLS AND OTHER ASSOCIATED INFORMATION

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[21] Appl. No.: 721,167

[22] Filed: Jun. 26, 1991

[51] Int. Cl.⁵ G06F 15/21

[52] U.S. Cl. 364/401; 364/406

[58] Field of Search 364/401, 406, 408

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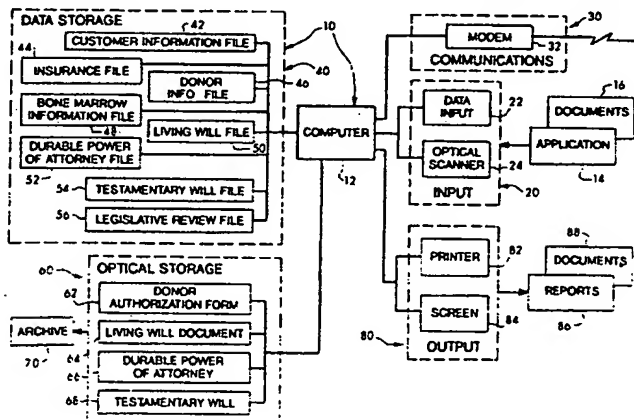
Attorney, Agent, or Firm—Dorr, Carson, Sloan & Peterson

[57]

ABSTRACT

A central depository for secure storage and rapid retrieval of important documents and information, such as living wills, durable powers of attorney, testamentary wills, authorization for organ donation, authorization of bone marrow donation, and insurance information. The depository includes a data storage facility having a computer and Write Once, Read Many (WORM) drive CD-ROM player connected to an optical scanner. The documents are scanned by the optical scanner and stored on the CD-ROM player. Other information is entered into data storage facilities connected to the computer. Requests for information can be received by the depository from remote locations by data transmission devices, such as telephone, facsimile, postal service, or electronic mail. The system also provides a procedure for updating the information and documents as legislation regarding the stored information and documents changes. Also, the system monitors for changes in residence which may affect the information and documents.

27 Claims, 6 Drawing Sheets



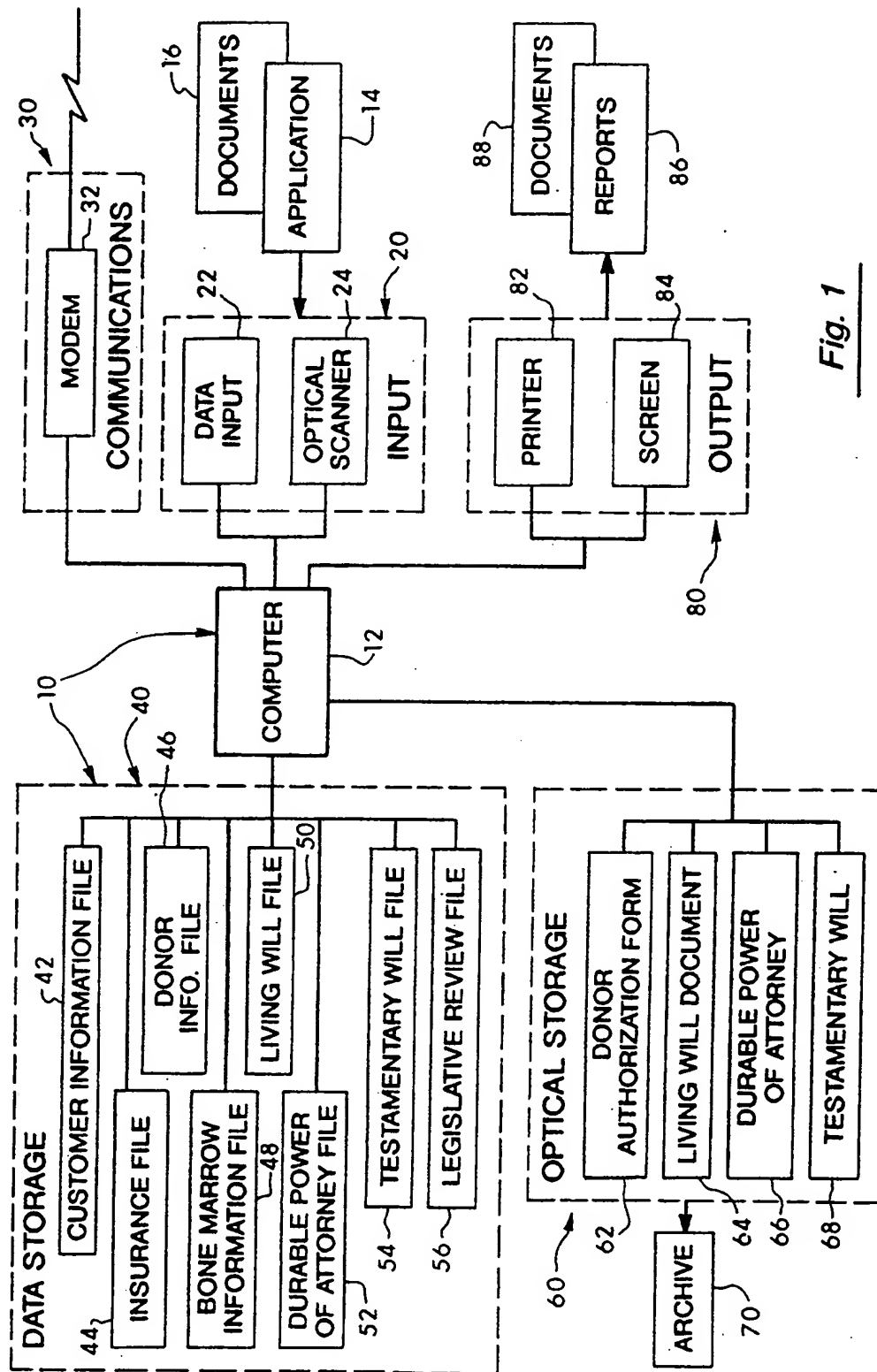


Fig. 1

Fig. 2

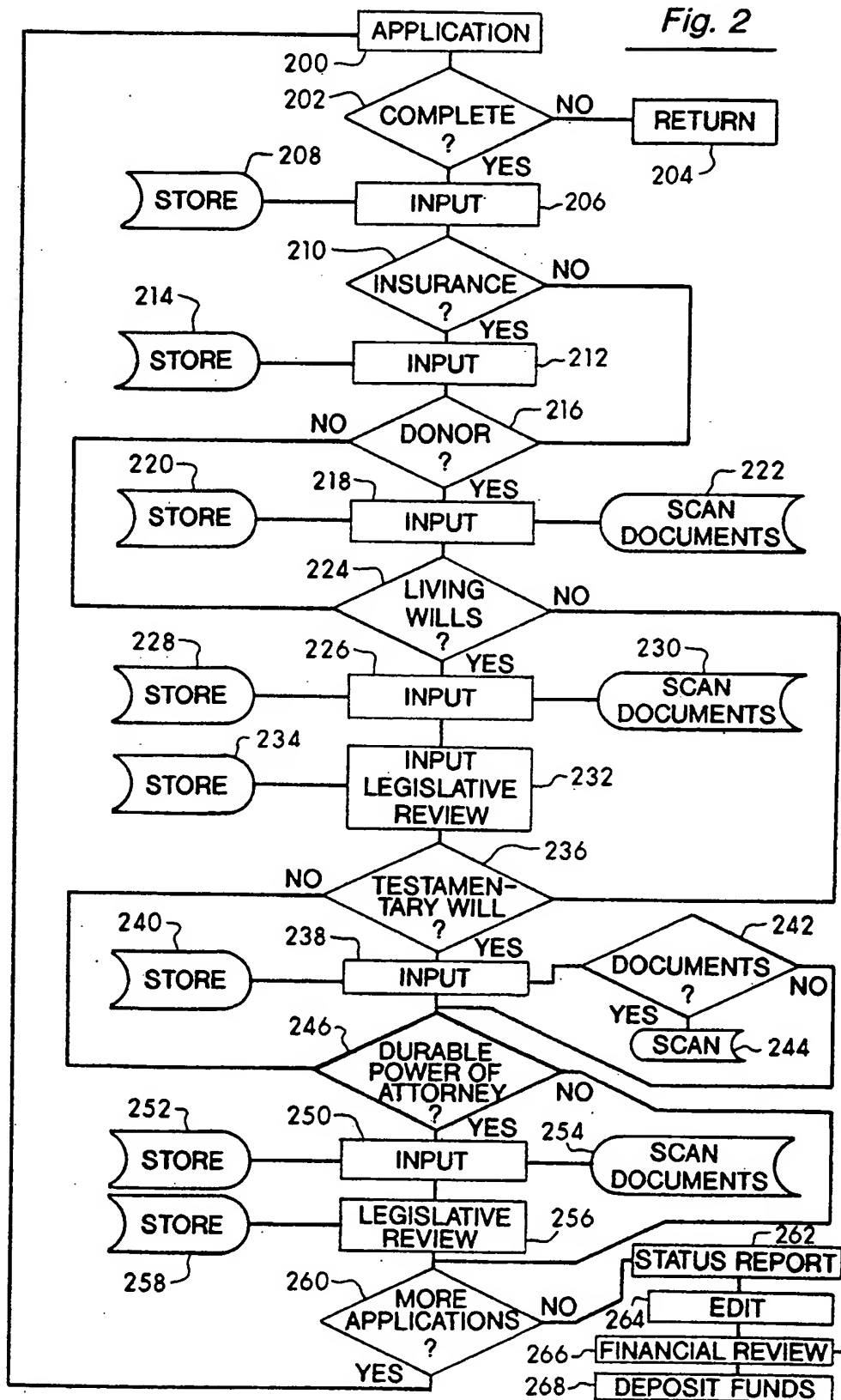


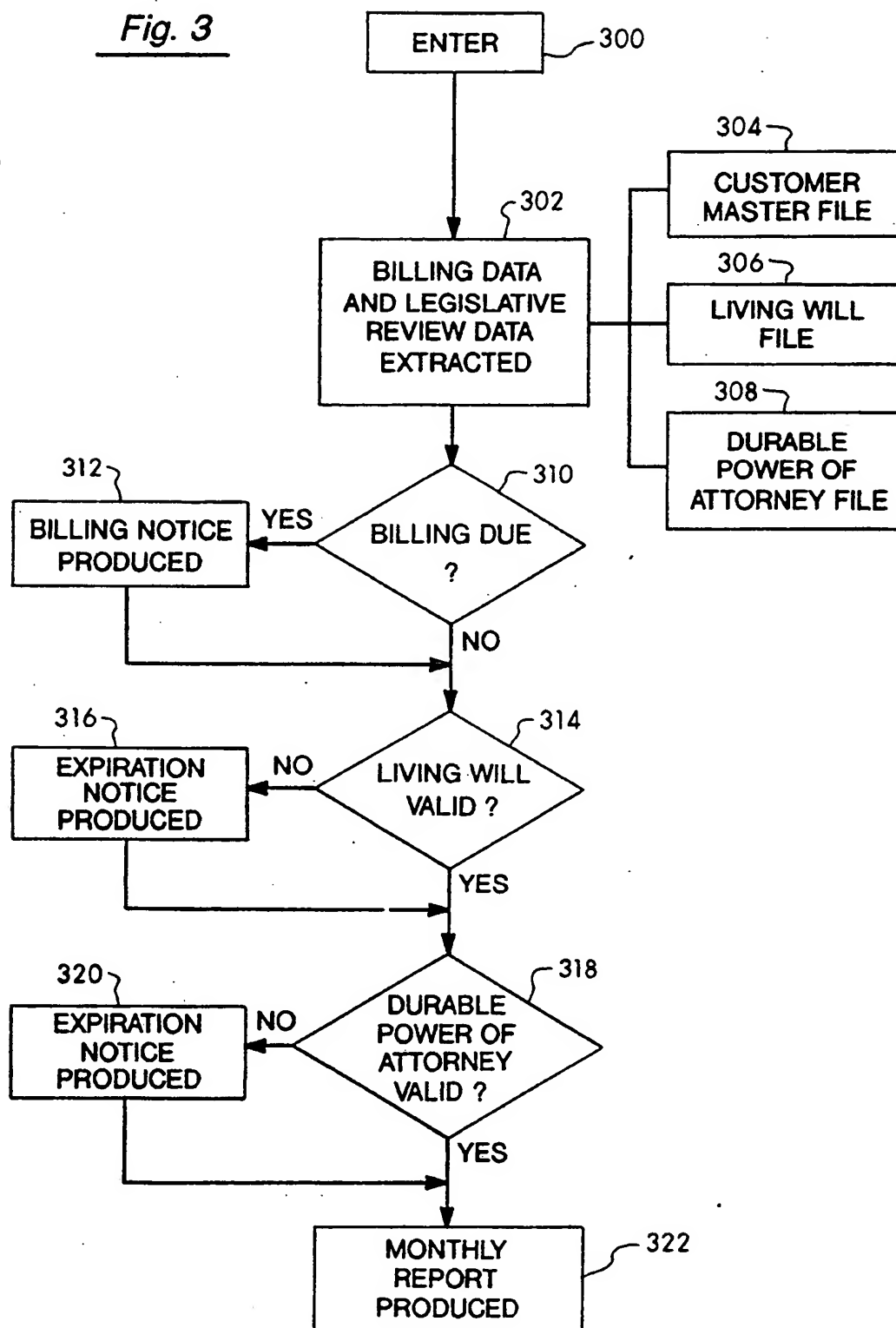
Fig. 3

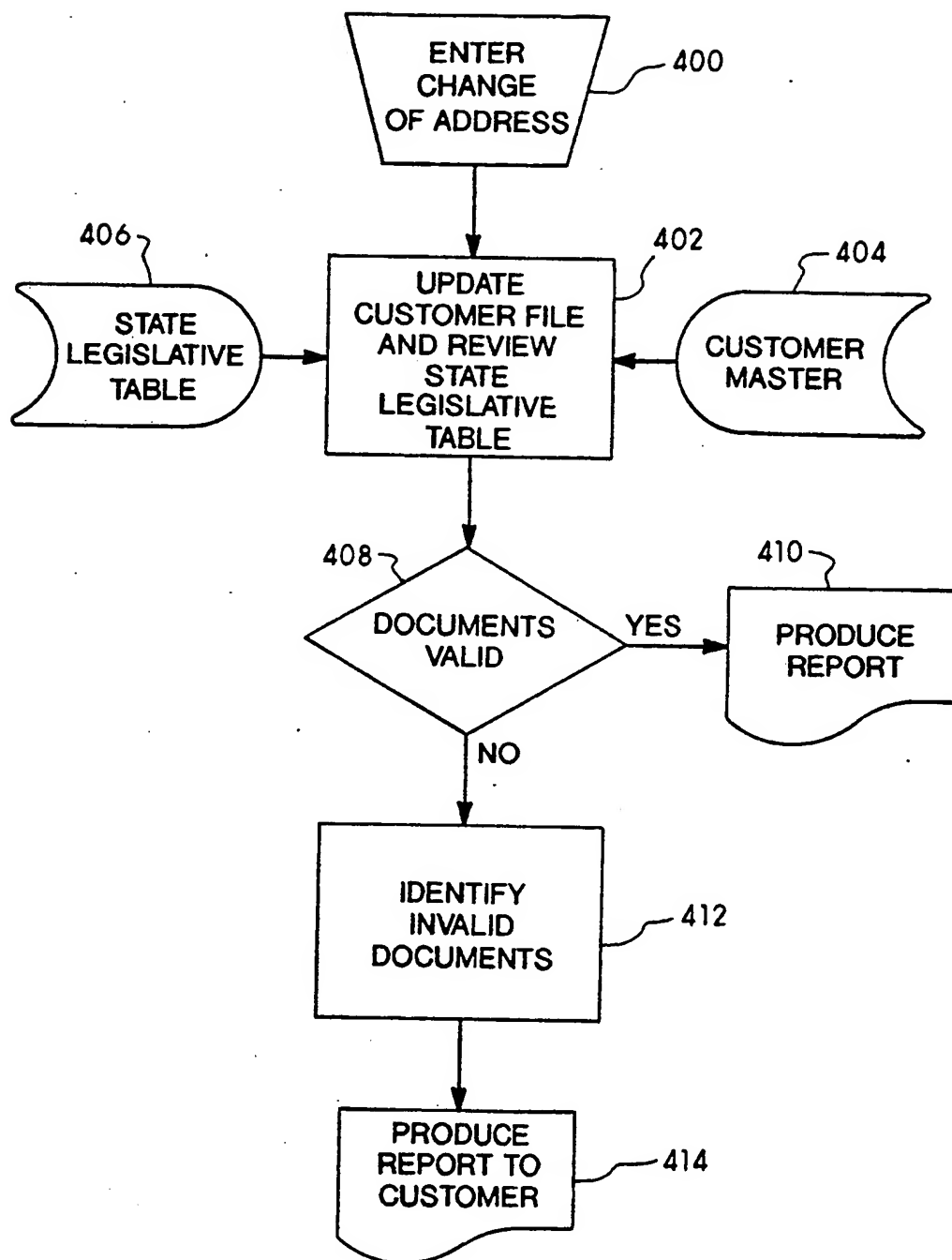
Fig. 4

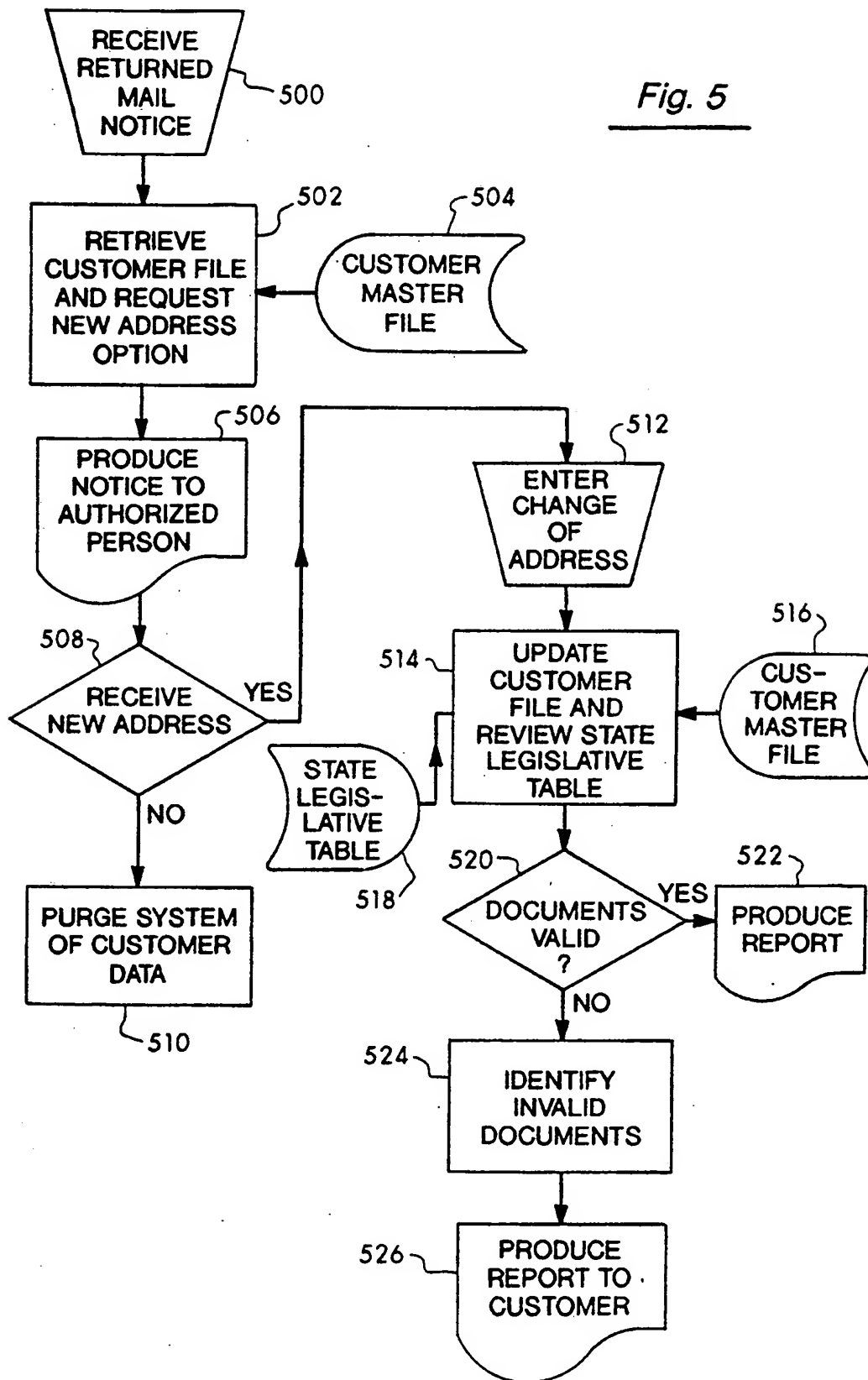
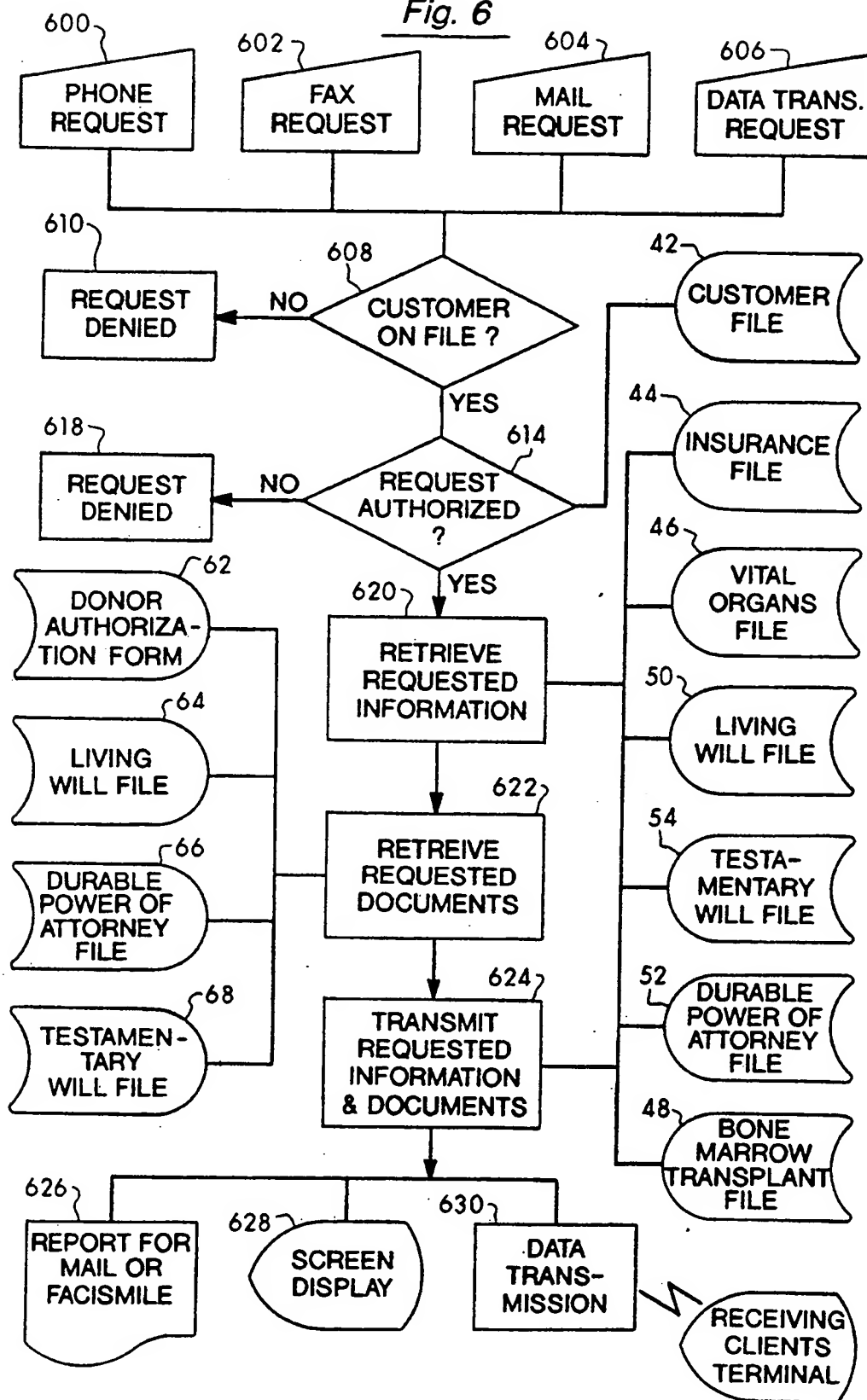
Fig. 5

Fig. 6



SYSTEM FOR ADMINISTERING A CENTRAL DEPOSITORY FOR LIVING WILLS AND OTHER ASSOCIATED INFORMATION

BACKGROUND OF THE INVENTION

1. Field of the Invention:

The present invention relates to the field of central depositories for living wills, testamentary wills, durable powers of attorney, insurance information and organ and donor data banks.

2. Statement of the Problem:

In times of emergencies, there is often an urgent need for immediate access to important documents. For instance, the general public is becoming aware of their right to refuse medical treatment or terminate life support systems, in the event of imminent death or permanent unconsciousness. However, this right needs to be expressed in advance, through documents such as a living will and durable power of attorney.

These documents are typically, if at all, created, executed and filed in a haphazard manner, with little regard to their accuracy or uniformity, or to ease of access, security or to updating the documents for legal sufficiency in case of legislative changes or changes of residential jurisdiction. The documents are created in an individual manner and then filed away where they can be lost or destroyed. At best the documents are stored in a safety deposit box with limited access thereto. Generally, relatively few people provide for ready access to these documents, or other documents, such as living wills, testamentary wills and/or organ and blood marrow donor forms, at the times of crisis when these documents are most needed.

This is particularly true in today's mobile society where catastrophic accidents or illnesses can occur in locations away from home. An individual can be involved in a catastrophic accident or illness in a location far from home, and the treating medical facility will be unable to gain access to the necessary documents. Also, valuable time can be wasted in the instance of organ donations in trying to gain authorization from relatives.

These documents may also need to be periodically reviewed and revised as the laws change or situations are altered. The documents may be legally sufficient at the time of execution, but as legislation changes, the documents may be no longer valid. Also, a document executed in one jurisdiction may not be valid in another jurisdiction where the individual later resides.

In the situation of accidents or death, it may be difficult to verify insurance coverage, including health insurance and life insurance. Life insurance policies are often stored in inaccessible locations, thus slowing the benefit payments. Also, it may be awkward to verify health insurance coverage for treatment in remote locations.

Another related problem is in finding compatible donors for bone marrow transplants. Typically, in the instances where a bone marrow transplant is necessary, the donee must ask for volunteers. There is no central index for potential donors to be cross-typed according to compatibility.

Therefore a need exists for a central depository which can solve these and other problems.

SOLUTION TO THE PROBLEM

The present invention provides a national depository for filing of such documents as living wills, durable

powers of attorney and collateral data bases of testamentary wills, insurance information and organ and bone marrow donors.

The present invention provides a data processing system to store such documents as well as information about the individual that may be necessary in times of crises.

The present invention provides a system that can manage these documents and provides information to verify the documents for accuracy and legal requirements.

The present invention provides a system that can periodically review for legislative updates.

The present invention provides a system that can periodically review and verify for changes of address and situations.

The present invention provides a system that can process requests for stored information and retrieve such information for authorized requestors.

The present invention provides a system that can transmit such requested information directly to the requestor.

These and other solutions are provided by the present invention as will become evident from the ensuing description of the invention taken in conjunction with the drawings.

SUMMARY OF THE INVENTION

The present invention provides a central depository for secure storage and rapid retrieval of important documents and information. This includes such items as living wills, durable powers of attorney, testamentary wills, authorization for organ donation, authorization of bone marrow donation, and insurance information.

One preferred embodiment of the present invention includes a data storage facility having a computer and optical storage device connected to an optical scanner. The documents are scanned by the optical scanner and stored in an optical storage facility. Other information is entered into data storage facilities connected to the computer. Requests for information can be received by the depository from remote locations by data transmission devices, such as telephone, facsimile or electronic mail. The depository will process these requests, to verify that the request applies to a customer of the depository, and that the person making the request is authorized to receive the information. The authorized request for information and documents can then be processed and the appropriate information and documents retrieved and transmitted to the person making the request.

The system also provides a procedure for updating the information and documents as legislation regarding the stored information and documents changes. Also, the system monitors for changes in residence which may affect the information and documents.

The system of the present invention provides a secure depository for important information and documents which may be rapidly retrieved from almost any geographical location.

These and other features of the claimed invention will become evident from the ensuing detailed description of a preferred embodiment taken in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows an overview of a preferred embodiment of the present invention.

FIG. 2 is a flow chart of the application process of the present invention

FIG. 3 is a flow chart of the periodic updating of the system.

FIG. 4 is a flow chart of the updating of documents after a change of address.

FIG. 5 is a flow chart of the tracing procedure of the system.

FIG. 6 is a flow chart of the request processing procedure of the system.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

1. Overview of a Preferred Embodiment

The present invention provides a central depository for important documents, such as living wills (expressing and authorizing the "right to die"), durable powers of attorney and other collateral documents including testamentary wills, authorizations for organ and bone marrow donations, and insurance information. The general public has increasingly become aware of the need to express, in advance, the preference and right to refuse medical treatment in the event of imminent death or permanent unconsciousness. The present invention provides a safe central repository for such "right to die" documents, including living wills and durable powers of attorney and a system for management and retrieval of these documents and associated information. This system is also suited as a repository for related documents such as testamentary wills and authorizations for organ and bone marrow donations as well as information such as health and life insurance.

A general overview of a preferred embodiment of the present invention is illustrated in FIG. 1. It is to be expressly understood that this descriptive embodiment is for explanatory purposes only and is not meant to limit the scope of the claimed inventive concept. Other variations and embodiments are considered to be within the scope of the inventive concept.

2. System Configuration of a Preferred Embodiment

The central depository 10, shown in FIG. 1, can be physically located at almost any location. The depository includes computer 12 having data input 20. Input 20 includes data input device 22, such as a keyboard or mouse, and optical scanner 24, for processing applications. The application information 14 can be manually entered through the data input device 22 while any documents 16 can be scanned in by optical scanner 24. Communications device 30, which includes modem 3, inputs information into computer 12; in addition, it receives requests for information and documents and transmits information from the system.

The information from the application is verified by computer 12 and stored in data storage 40. Separate files are set up for each customer according to the desired service. Customer document file 42 is set up to store information on each particular customer, such as background information, billing information and identifying information as discussed in greater detail below. Insurance file 44 is set up to store information relating to life insurance and health insurance if the customer desires. Information regarding potential organ donation is stored in donor information file 46. Bone marrow infor-

mation file 48 is set up for information on potential bone marrow transplant donors. Living will information is stored in living will file 50 and durable power of attorney information is stored in durable power of attorney file 52. Testamentary will file 54 is set up to store information regarding the testamentary will and codicils of the customer. Legislative review file 56 is set up to periodically review and update any necessary information and documents as legislation is updated.

Documents scanned by optical scanner device 24 are stored in optical storage 60. Many jurisdictions are recognizing, for legal purposes, documents stored on a Write-Once, Read-Many Times (WORM) drive CD-player, without requiring production of the original documents. Document stored on WORM-drives are unalterable; therefore, they should be sufficient for legal purposes. Documents relating to authorization for organ donation are stored in donor authorization form file 62. Living will documents are stored in living will document file 64. Durable power of attorney file 66 is set up to store durable power of attorney documents. Testamentary wills are stored in testamentary will file 68.

Archive 70 is available for physically storing the original documents. Archive 70 will typically be a fire-proof vault or underground cavern or the like to securely store the original documents.

Depository 10 further includes computer output 80. Output 80 includes printer 82 to print out the stored information, documents 86, and reports 88 and screen device 84. Communications device 30 also can serve as an output device for computer 12 to directly transmit data to remote locations.

Computer 12 includes operating systems, discussed in greater detail below, to verify the applications for accuracy and completeness, for entering information and documents to the appropriate files, and for processing requests for information and documents. Computer 12 also periodically reviews the files and documents for legislative updates and for jurisdictional requirements in regard to customer changes of residences. Billing systems are also in place to alert customers to upcoming fees and to bill the customers for such fees. The system is also capable of updating customer information as necessary and purging the depository of any information and documents regarding inactive customers.

Processing the application:

Depository 10 typically operates as illustrated in FIGS. 2-5. As indicated in the chart illustrated in FIG. 2, the customer sends to depository 10, as indicated in block 200, a completed application form including information, such as the customer's name, date of birth, social security number, current address, mother's maiden name, next of kin, and insurance information, as well as the necessary documents, such as a living will, durable power of attorney, testamentary will and authorization for donation of organs and bone marrow. This application is received at the receiving office of depository 10 where it is processed, at decision block 202, either manually or by a computerized system. The information is checked for completeness as well as obvious errors. If the information is incomplete or in error, the application, at block 204, is returned to the customer with a request for additional information. Once the application is complete, the information and documents are entered, at block 206, into the depository.

A customer information file 42 is created for each customer and a unique file number is assigned with a code identifying the state of residence of the customer. This could be the customer's social security number or a number generated by the depository. Initially, the customer's reference information is entered into the system. This reference information includes such information as the customer's name, date of birth, social security number, current address and mother's maiden name or other significant identifying information. This information, at block 208, is stored in customer information file 42.

The system then moves to decision block 210 for insurance information. If the customer does not desire insurance information to be stored, then the system will move on to decision block 216 for organ donor authorization. However, if requested by the customer, insurance information is entered, at block 212, into the system. The insurance information will be stored, at block 214, in insurance file 44. This will allow for the retrieval of critical information for prompt notification of the insurance company at the time of need or death and to insure that all benefits or proceeds are made immediately available to the appropriate parties.

The next step, at decision block 216, is to determine whether organ and bone marrow donation is to be authorized. If the customer does not wish to authorize organ donation, then the system moves to decision block 224 for living wills. However, if the customer wishes to authorize organ donation, then the system, at block 216, will identify which vital organs are desired to be donated as well as the possible use of the customer's body for potential scientific study. This information is stored, at block 220, into donor information file 46. Donor authorization forms, if necessary, are scanned at block 222 and stored in optical storage 60 in donor authorization form file 62.

Also, at block 218, if the customer wishes to be indexed for potential bone marrow transplants, then this information will be stored, again at block 220, in bone marrow information file 48. This information will be available to authorized individuals who are on a list of those individuals who have been typed for bone marrow transplants and are willing to be available for such transplants. This information would be available immediately to streamline the matching of potential donors and recipients.

The system, at decision block 224, determines if living will information and documents are to be entered into the system. If the customer does not desire this service, then the system moves to decision block 236 for testamentary wills. If the customer wishes to store living will documents, then the system inputs living will information at block 226 into the system. The living will expresses the customer's right and preference to have medical support terminated under certain detailed conditions, involving imminent death or permanent unconsciousness. Information regarding the customer's living will is stored at block 228 into living will file 50. The living will documents are stored, at block 230, into optical storage 60, in living will document file 64.

The system next inputs, at block 232, legislative review information into the system. The legal requirements for living wills may differ from state to state. Therefore the living will information is checked relative to the requirements of the state in which the customer resides. This information is readily flagged by the unique identification code on the customer's file. Also,

the system is able to verify, as discussed in greater detail below, the customer's documents for validity as legislation is updated. This information is stored, at block 234, in legislative review file 56.

The system, at decision block 236, determines if the customer wishes information and documents relating to their testamentary will and codicils stored. The system moves to decision block 246 if the customer this service, then information regarding the testamentary will and codicils is entered, and then stored at block 240 into testamentary will file 54. At decision block 242 the system determines whether there are documents to be scanned. If not, then the system moves on to decision block 246 for durable power of attorney. If there are documents to be scanned, then these documents are stored, at block 244, into optical storage 60 in testamentary will file 68.

The system at block 246 determines whether to input information and documents relating to the durable power of attorney. This typically is a companion document to the living will and testamentary will. A durable power of attorney creates a power of attorney which will survive incapacitation of the customer. This is necessary in order for the appointee to be able to execute the wishes of the living will. If storage of a durable power of attorney is not desired, then the system moves on to decision block 260. If a durable power of attorney is to be stored, then information and documents regarding the durable power of attorney is entered, at block 250. The information is stored, at block 252, into durable power of attorney file 52. The documents are scanned, at block 254, into optical storage 60, in durable power of attorney file 66.

The system inputs, at block 256, legislative review information regarding the durable power of attorney. Legal requirements differ from jurisdiction to jurisdiction and may periodically be revised. The system verifies the accuracy of the customer's durable power of attorney according to their residential jurisdiction and periodically verifies these documents as legislation is revised. This information is stored, at block 258, into legislative review file 56.

The original documents are either sent back to the customer (not shown), or if the customer requests, stored in an safe and secure archive 70 operated by the depository.

The system, at decision block 260, determines if there are any more applications to be processed. If there are more applications to be processed, then the system moves back to block 200 and repeats the process as necessary. If there are no more applications waiting to be processed, then the system prepares a status report, at block 262. The system verifies that this report is correct and moves to block 266. If necessary, the report is edited, at block 264, then the system moves to block 266.

The system at block 266 reviews the financial status of the processed applications. The funds that were generated by the processing of the applications are then deposited, at block 268, in an appropriate location.

It is to be expressly understood that the embodiment described above is for explanatory purposes and is not meant to limit the scope of the inventive concept. For instance, the system of the present invention can process the information in any number of sequential steps and in any order of processing the information and documents.

Updating the system:

The system of the present invention provides the capability to periodically and automatically update the status of the files stored therein. The system does this by three procedures.

The first procedure, shown in FIG. 3, updates the legislative review data periodically. As the statutory requirements evolve in each jurisdiction, the system will note these changes. Periodically, or as legislation affecting the validity of stored documents is revised, the system will enter the customer files, as shown in block 300, in FIG. 3. The system, in block 302, will enter each customer's files, and, at blocks 304, 306, and 308, the system will extract billing data and legislative review data therefrom.

The system then enters decision block 310 to determine if billing is due to the customer. If not, then the system proceeds to decision block 314. If the customer is due to be billed, then a billing notice is produced at block 312. The system then moves on to decision block 314.

The system at decision block 314 determines if the living will is still valid after the legislative revisions. If the living will is still valid, then the system moves onto decision block 318. If the living will is no longer valid, then the system at block 316 produces an expiration notice for the customer. The system then moves onto decision block 318.

The system at decision block 318 determines if the durable power of attorney is still valid after the legislative revisions. If the durable power of attorney is still valid, then the system moves onto block 322 to produce a monthly report. If the durable power of attorney is no longer valid, then the system at block 320 produces an expiration notice. The system then moves onto block 322.

At block 322, the system produces a monthly report of all activities generated by the system and the status of the files and documents.

The second updating procedure also occurs, shown in FIG. 4, automatically. Once a customer changes address and sends in a change of address to the system, this change of address is entered into the system, as indicated in block 400. Customer information file 42, in block 404, is retrieved, and the new change of address, in block 402, is updated. Also in block 402, information from legislative review file 56, retrieved in block 406, is reviewed. The system, in block 408, reviews the documents which have been previously stored to determine whether they are still valid in the new residential jurisdiction. If the documents are still valid, then the system, in block 410, produces a report to this effect. If the documents are no longer valid, then the system in block 412 identifies the documents which are no longer valid. A report, in block 414, is produced and sent to the customer identifying the invalid documents and requesting new documents to be executed.

The third procedure, illustrated in FIG. 5, involves a tracing procedure for customers who have moved without notifying the depository of their change in address. Each customer is periodically billed for the costs of the depository service. A returned mail notice is entered into the system, at block 500, if the bill is returned because the customer is no longer at that address. The system then, at block 502, retrieves customer information file 42, in block 504, and requests the new address option. The new address option includes the name and address of a person or entity that the customer designated who will provide notification of the whereabouts of the cus-

tomers. Typically this will be a close relative, or someone to be notified in the event of an emergency. The system produces a notice, in block 506, to the designated person or entity requesting a new address for the customer. After a predetermined passage of time, the system moves to decision block 508 to determine whether a new address for the customer has been received. If a new address has not been received, then the system moves to block 510 to purge the system of the customer data and documents. Normally the system will move the information files and document files to an inactive status for a designated period of time after which the system will purge all information and documents from the system.

If a new address for the customer is received, then the system, in block 512, will enter the change of address into the system. The customer information file 42, in block 516, will be retrieved and updated, in block 514, with the new address. In block 514, the system will also retrieve legislative review file 56 to review the jurisdictional requirements for the stored documents. In decision block 520, the system will determine whether the documents are still valid in the new residential jurisdiction. If the documents are still valid, then in block 522 the system will produce a report to that effect.

If the documents are no longer valid, then, in block 524, the system will identify which documents are no longer valid. The system will then, in block 526, produce a report to the customer identifying the invalid documents and requesting new executed documents to be sent to the depository.

Utilization of these procedures provides the customer with automatic and periodic verification and update on the status of the information and documents stored in the depository.

Processing requests for information:

The depository system provides rapid processing of requests for the information and documents stored there. The processing operation is shown in FIG. 6. A telephone request, in block 600, facsimile request, in block 602, mail request 604, or other data transmission request 606, for information or documents regarding a particular customer is received and entered into the system.

The system, in decision block 608, first verifies that the person on which the information or documents is requested is a customer of the depository. If the person is not a customer, then, in block 610, the request is denied. If the person is a customer, then, in block 614, the system verifies that the person or entity making the request is authorized to receive the information and documents. This is done by retrieving customer information file 42 and checking for prior authorization or for prior authorized procedures. If the person or entity making the request is not authorized to receive the information or documents, the request, in block 618, is denied.

Once a request has been authorized, then the system moves to block 620 to retrieve the requested information from insurance file 44, organ donation file 46 bone marrow transplant file 48, living will file 50, durable power of attorney file 52 or testamentary will file 54. The system then in block 622 retrieves requested documents from authorization form file 62, living will document file 65 durable power of attorney file 66 or testamentary will file 68.

The retrieved information or documents are then, in block 624, transmitted via the appropriate transmitting

device to the person or entity making the request. Documents and reports can be transmitted in block 626 via mail or facsimile transmission. Information can also be transmitted via screen display, in block 628, directly over telephone requests. Also the information data can be directly transmitted over the communications device 30, in block 630, to a receiving terminal.

Billing systems are utilized (not shown) to charge the appropriate fees for the services.

Examples of the processing of requests for various information and documents are described below. It is to be expressly understood that these examples are for descriptive purposes only and are not meant to limit the scope of the claimed inventive concept. The system of the present invention is capable of various embodiments and modifications and the below described examples are for explanatory purposes only.

Example of request for living will:

A request for the living will documents is received by the processing system by a toll-free 800 number, facsimile, mail, electronic mail or other data transmission devices. The request is checked against the customer file. If the information is on file, then the requesting entity can be notified, if a toll-free 800 number was used, to call a "900" telephone number, for billing purposes, or other payment/billing device to receive the information.

After the requesting entity has done so, then the processing system verifies that the requesting entity is authorized to receive the information and documents. This may be by prior authorization contained in the customer's files, or by operation of law.

If the requesting entity is authorized to receive the information and documents, then the information is retrieved and transmitted to the requesting entity. This can be by electronic transmission, by telephone, by facsimile or other data transmission devices. The documents can be retrieved from the optical storage device and mailed to the requesting entity.

The center will purge the information and documents from the system, once it has been notified that the customer is deceased.

Example of inquiry for organ donation: customer's desire to donate organs or body portions should the customer be declared dead. At the appropriate time, a medical facility may call an "800" number to verify if a patient is a customer of the center. This can be done by an automatic answering device. If the center verifies that the patient is a customer, then the medical facility is given further instructions to call a "900" number or another data transmission device.

The medical facility will provide pertinent information as to the customer, such as name, social security number, date of birth and the like. If that customer has indicated their desire to be a donor, then the center will provide to the requesting facility, if authorized, a copy of the donor card and information by electronic transmission or other data transmission devices. If necessary, a certified copy of the original document will be provided from the archives or from the optical data storage.

Example of request of compatibility typing:

The appropriate entity, normally a medical facility or medical doctor, calls the "800" number for inquiries as to whether a person is a customer of the center, in the case of organ donation, or if a specific Human Leukocyte Antigen (HLA) type is available, for bone marrow donation. The caller can ascertain from the answering

device whether a particular person is a client of the center, or if there is a particular HLA type noted for potential bone marrow donation.

In the event that there is an affirmative answer to the caller's inquiry, the caller will be instructed to call a "900" number to make the desired request for information or documents. The caller will provide information, including the identity of the caller and reason for requesting the information. The system will verify to ascertain whether the caller is authorized to receive the requested information or documents, either by prior authorization from the customer's files or by operation of law.

If the caller is authorized to receive the information, then the system will verify that the customer has requested that information regarding their Human Leukocyte Antigens (HLA) typing be provided to appropriate medical facilities or doctors. The HLA typing provides an indication of the compatibility between potential organ donors and recipients and potential bone marrow donors and recipients.

The customer can also indicate that they be notified for permission prior to such information being provided. If the request is authorized, then upon payment, via "900" telephone charge or other payment system, the information is transmitted to the caller.

Example of request for testamentary will:

The caller calls the "800" number to ascertain whether a person is a customer of the center. The individual can ascertain from the answering device whether a particular person is a customer of the center.

In the event that there is an affirmative answer to the individual's inquiry, the individual will be instructed to call a "900" number to make the desired request for information or documents. The caller will provide information, including the identity of the caller and reason for requesting the information. The system will verify to ascertain whether the caller is authorized to receive the requested information or documents, either by prior authorization from the customer's files or by operation of law.

If the caller is authorized to receive the information, then a copy of the information, such as the testamentary will, is transmitted to the caller after a charge has been made via the "900" telephone service.

The original of the testamentary device, or a certified copy, can be provided upon receipt of a certified copy of the death certificate of the customer. The death certificate information will be entered into the system and the customer will be removed from the active files to the inactive files, and eventually purged from the system.

If the caller is not authorized to receive the information, then they can send a written request stating reasons for needing the information, a certified copy of the death certificate, and the appropriate fee. A copy of the testamentary device may then be transmitted to the requestor.

Example of request for insurance information:

The caller calls the "800" number to ascertain whether a person is a customer of the center. The individual can ascertain from the answering device whether a particular person has information, such as a Living Will, Durable Power of Attorney, insurance information, organ donation information or testamentary will, stored at the center.

In the event that there is an affirmative answer to the individual's inquiry, the individual will be instructed to

call a "900" number to make the desired request for information or documents. The caller will provide information, including the identity of the caller and reason for requesting the information. The system will verify to ascertain whether the caller is authorized to receive the requested information or documents, either by prior authorization from the customer's files or by operation of law.

If the caller is authorized to receive the information, then a copy of the information, such as health insurance if the customer has been in an accident or sudden illness, is transmitted to the caller after a charge has been made via the "900" telephone service.

Likewise, life insurance policy coverage can be ascertained via the same procedure. Also, once a certified copy of the death certificate is provided to the center, a copy of the life insurance policy, or the original if necessary, can be transmitted to the beneficiaries.

The present invention provides a central depository for providing secure storage and rapid access to important documents and information, and a system for administering this depository. The system as claimed is not meant to be limited to the above description of a preferred explanatory embodiment, but encompasses other embodiments and modifications. The claimed invention is not meant to be limited for use with only the above described documents and information but further encompasses other documents and information as the need arises.

We claim:

1. A system for administering a central depository for living wills and other associated documents and customer information for health care purposes, said system comprising:

data storage means for storing documents and customer information, said documents including said living wills and other associated documents;

means for entering said documents into said data storage means;

means for entering said customer information into said data storage means;

means for verifying that said documents fulfill the legal requirements of said customer's residential jurisdiction;

means for periodically updating said legal requirements and verifying that said documents still fulfill the legal requirements of said customer's residential jurisdiction;

means for processing requests for said documents and said customer information from said data storage means;

means for retrieving said documents and customer information in response to said requests; and

means for transmitting said requested documents and customer information.

2. The system of claim 1 wherein said documents include durable powers of attorney for health care purposes.

3. The system of claim 1 wherein said other associated documents further include testamentary wills, insurance policies and authorization forms for organ and bone marrow donation.

4. The system of claim 3 wherein said system further comprises means for entering information regarding potential organ and bone marrow donors of said customers; and

means for indexing said information regarding organ and bone marrow donors of said customers according to specific types.

5. The system of claim 1 wherein said means for entering said documents include an optical scanning device.

6. The system of claim 5 wherein said data storage means include a CD-ROM player device for storing said documents scanned by said optical scanning device.

7. The system of claim 1 wherein said system further includes means for verifying said documents and said customer information for completeness, for errors, and for legislative changes.

8. The system of claim 1 wherein said system further includes means for updating changes of said residential addresses of said customers.

9. The system of claim 1 wherein said system further includes

means for preparing billing information in regard to said customers information as well as the current status of said stored documents and customer information; and

means for providing said billing information and status to said customer.

10. The system of claim 1 wherein said system further includes means for updating any new customer information and means for purging information relating to inactive customers from said system.

11. The system of claim 1 wherein said means for processing requests includes:

means for receiving said request for information and documents pertaining to a particular customer;

means for verifying that information is present in said data storage means for said particular customer;

means for retrieving said requested information and documents from said data storage means; and

said transmitting means delivering said requested information and documents to the entity making said request.

12. The system of claim 11 wherein said means for processing requests further includes:

means for verifying that said entity making said request is authorized to receive said requested information prior to transmitting said requested information and documents.

13. The system of claim 1 wherein said means for transmitting said information includes:

means for transmitting data to a remote data receiving terminal.

14. A system for administering a central depository for living wills, durable powers of attorney for health care purposes, and other associated documents and customer information; said system comprising:

data storage means for storing documents and customer information, said documents including said living wills, durable powers of attorney, and other associated documents;

optical scanning means for entering said documents into said data storage means for storage;

means for entering said customer information into said data storage means for storage;

means for receiving requests for information and documents pertaining to a particular customer;

means for verifying that information is present in said data storage means for said particular customer;

means for verifying that the requestor is authorized to receive the requested information and documents;

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means for verifying said information and documents for completeness, errors, and that said documents fulfill any jurisdictional legal requirements; means for periodically updating said verification for legal requirements; means for retrieving the requested information and documents; and means for transmitting the requested information and documents to said requestor.

15. The system of claim 14 wherein said system further comprises:

- means for updating information relating to customers having documents and information stored in said system; and
- means for updating legal requirements for each customer.

16. The system of claim 14 wherein said system includes:

- means for preparing billing information for said customers;
- means for preparing status reports for said customers;
- means for updating information relating to said customers; and
- means for purging the system of documents and information of inactive customers.

17. A method of administering a central depository for living wills, durable powers of attorneys, and other associated information, said method comprises the steps of:

- processing an application from a customer;
- entering documents pertaining to said customer into an archival system, said documents including said living wills and said durable powers of attorney, wherein said step of entering documents into an archival system including the steps of:
 - (a) scanning said documents by an optical scanning device; and
 - (b) storing said scanned documents in a data storage means;
- entering information regarding said customer into said data storage means; wherein said step of entering information regarding said customer into said data storage means further includes the steps of:
 - (a) periodically entering information regarding legislative review pertaining to said documents into said system; and
 - (b) periodically verifying the legal sufficiency of said documents in response to said legislative review information;
- processing requests for documents and information regarding said customer;
- retrieving documents and information in response to said requests;
- transmitting said requested documents and information to the entity making said requests.

18. The method of claim 17 wherein said step of processing an application from a customer includes the steps of:

- verifying that said application is complete;
- verifying that said application is error-free; and
- verifying that any documents to be stored are legally sufficient.

19. The method of claim 17 wherein said step of storing said scanned documents in said data storage means includes storing said scanned documents in a CD-ROM player.

20. The method of claim 17 wherein said step of processing requests for information and documents of a particular customer includes the steps of:

14

verifying that documents and information regarding that particular customer exists in the archival system or the data storage means; and verifying that the request is authorized.

21. The method of claim 17 wherein said step of processing requests for documents and information includes the steps of:

- receiving said request for documents and information;
- verifying that documents and information for a particular customer is stored in said archival system or said data storage means;
- confirming to the entity requesting the documents and information that such documents and information exist; and
- notifying said entity of the procedure and charge to receive said documents and said information.

22. The method of claim 21 wherein said step of processing requests for documents and information includes the step of:

- verifying that the entity making the request is authorized to receive said requested information and documents.

23. The method of claim 17 wherein said step of transmitting said information and documents includes:

- transmitting said information and documents directly to a remote location.

24. A method of administering a central depository for living wills, durable powers of attorney, and other associated information, said method comprises the steps of:

- processing an application from a customer;
- entering documents pertaining to said customer into an archival system, said documents including said living wills and said durable powers of attorney;
- entering information regarding said customer into a data storage system;
- processing requests for documents and information regarding said customer;
- retrieving documents and information in response to said requests;
- transmitting said requested documents and information to the entity making said requests;
- periodically verifying the place of residence of said customers;
- updating any changes of address of said customers; and
- reviewing said documents and information for legal sufficiency in the new residential jurisdiction.

25. The method of claim 24 wherein said step of periodically verifying the place of residence of said customers further includes:

- tracing any change of address by contacting an authorized person in said customer's information for a new change of address.

26. The method of claim 25 wherein said method further comprises:

- placing any customer's information and documents in an inactive file should the customer's location be unable to be verified; and
- after a predetermined amount of time, purge said customer's information and documents from said inactive files.

27. The method of claim 24 wherein said method further comprises:

- indexing bone marrow type and organ types of any customer who desires to be a potential donor; and
- providing the indexed information to appropriate entities for possible cross-matching.

* * * * *



US005924074A

United States Patent [19]

Evans

[11] **Patent Number:** **5,924,074**[45] **Date of Patent:** **Jul. 13, 1999**[54] **ELECTRONIC MEDICAL RECORDS SYSTEM**[75] **Inventor:** Jae A. Evans, Carlsbad, Calif.[73] **Assignee:** Azron Incorporated, San Diego, Calif.[21] **Appl. No.:** 08/721,182[22] **Filed:** Sep. 27, 1996[51] **Int. Cl.⁶** **G06K 07/00**[52] **U.S. Cl.** **705/3; 705/2; 707/1; 707/3; 707/10**[58] **Field of Search** **705/3, 2; 707/1, 707/3, 10, 100, 102, 104**[56] **References Cited****U.S. PATENT DOCUMENTS**

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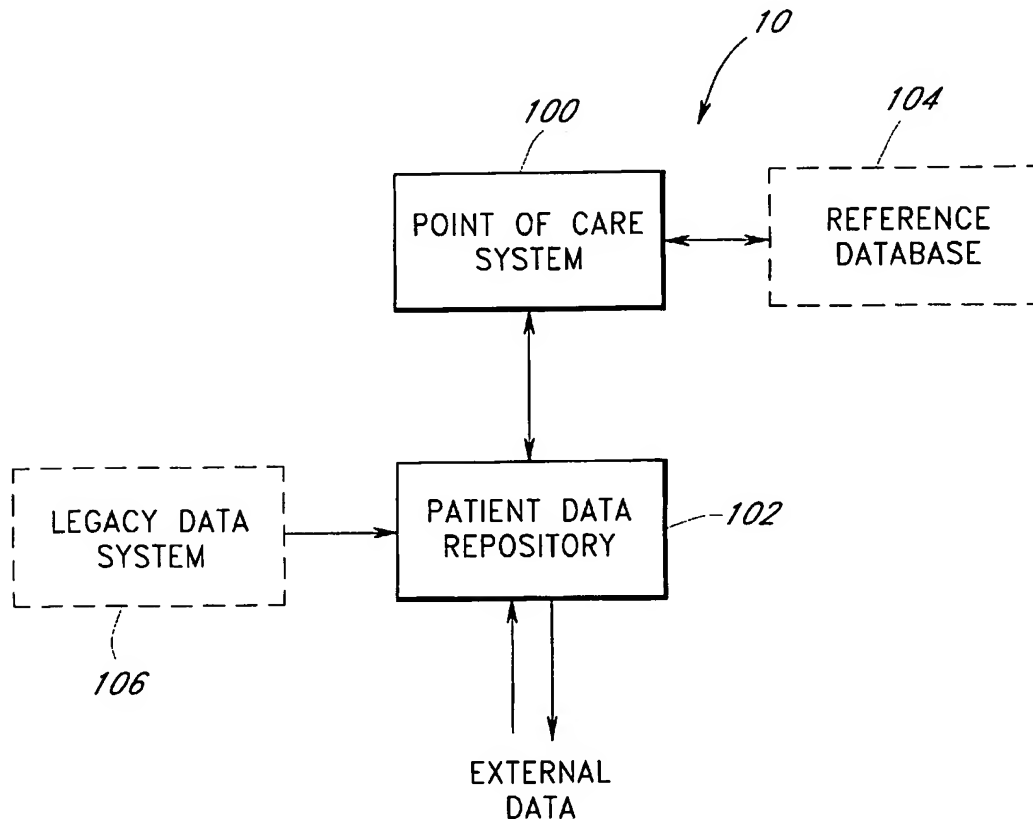
Declaration of Hollon H. Bridges, Jr., Dated Sep. 24, 1996, pp. 1-2.

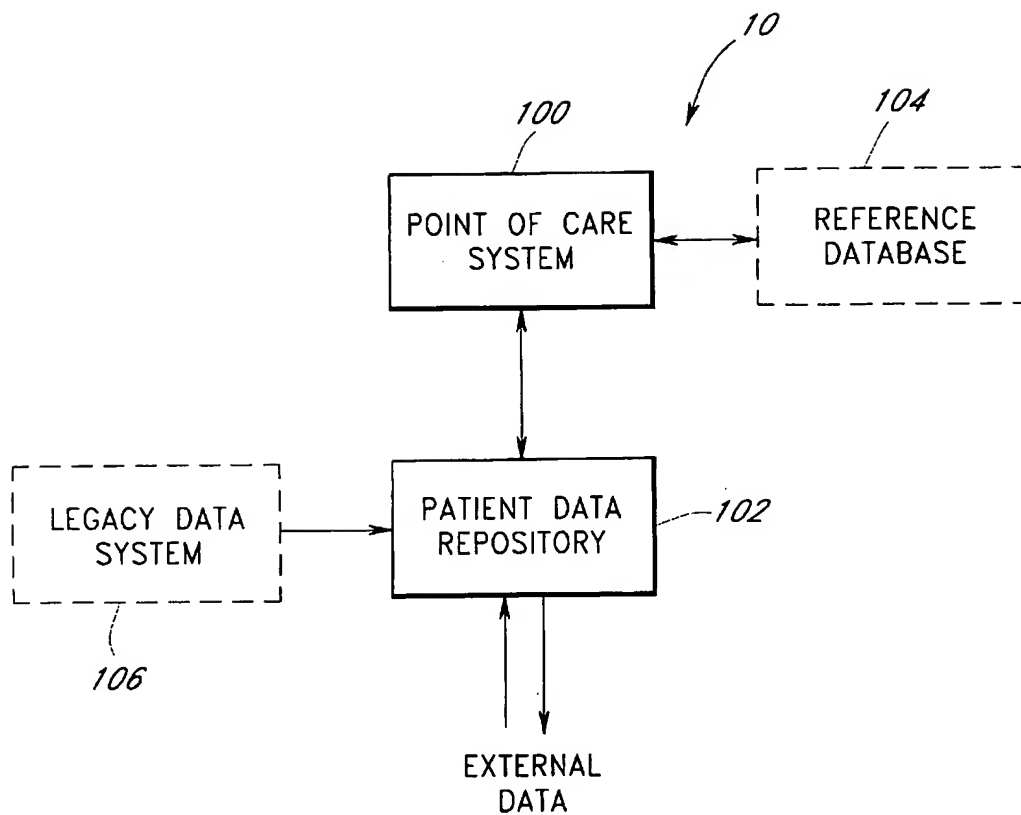
Declaration of Jae A. Evans, Dated Sep. 27, 1996, pp. 1-5 including Exhibit A, 1 p.

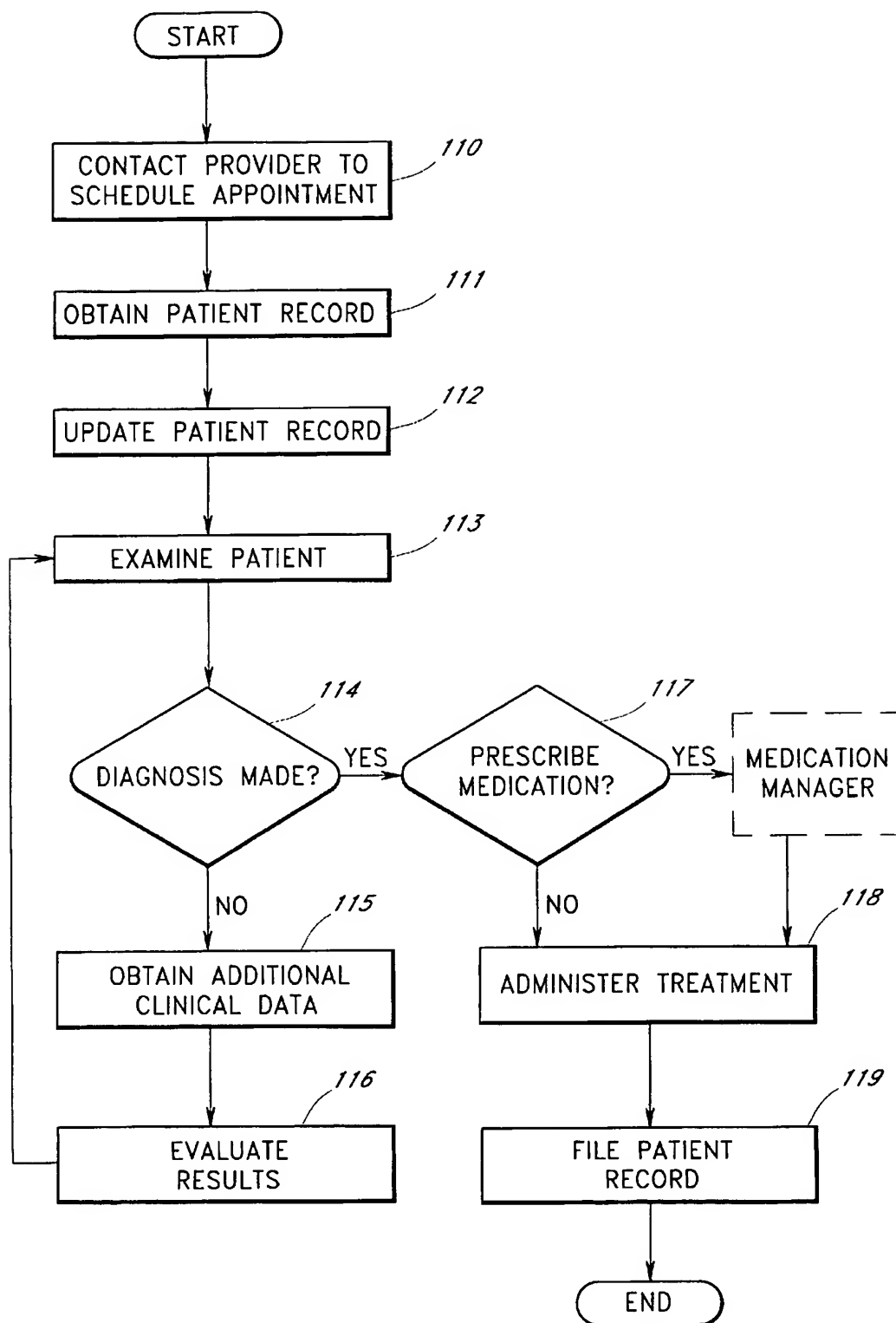
Declaration of Marion Neal, Dated Sep. 26, 1996, pp. 1-3.
 Declaration of David Printz, Dated Sep. 26, 1996, pp. 1-2.
 Kleinholz et al., "Supporting Cooperative Medicine: The Bermed Project," *IEEE MultiMedia*, vol. 1, No. 4, Dec. 21, 1994 pp. 44-53.

Primary Examiner—Thomas R. Peeso*Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear LLP[57] **ABSTRACT**

A medical records system that creates and maintains all patient data electronically. The system captures patient data, such as patient complaints, lab orders, medications, diagnoses, and procedures, at its source at the time of entry using a graphical user interface having touch screens. Using pen-based portable computers with wireless connections to a computer network, authorized healthcare providers can access, analyze, update and electronically annotate patient data even while other providers are using the same patient record. The system likewise permits instant, sophisticated analysis of patient data to identify relationships among the data considered. Moreover, the system includes the capability to access reference databases for consultation regarding allergies, medication interactions and practice guidelines. The system also includes the capability to incorporate legacy data, such as paper files and mainframe data, for a patient.

46 Claims, 26 Drawing Sheets

**FIG. 1**

**FIG. 2**

Azron Chart Puller

File Help

Please select an appointment or tell us about the new appointment.

Patient

Denson, Bob W. Select... Edit... Add...

Date: 08/14/1996 Time: 02:59 PM

Provider: Daley, Phil

Reason: Breathing Difficulties

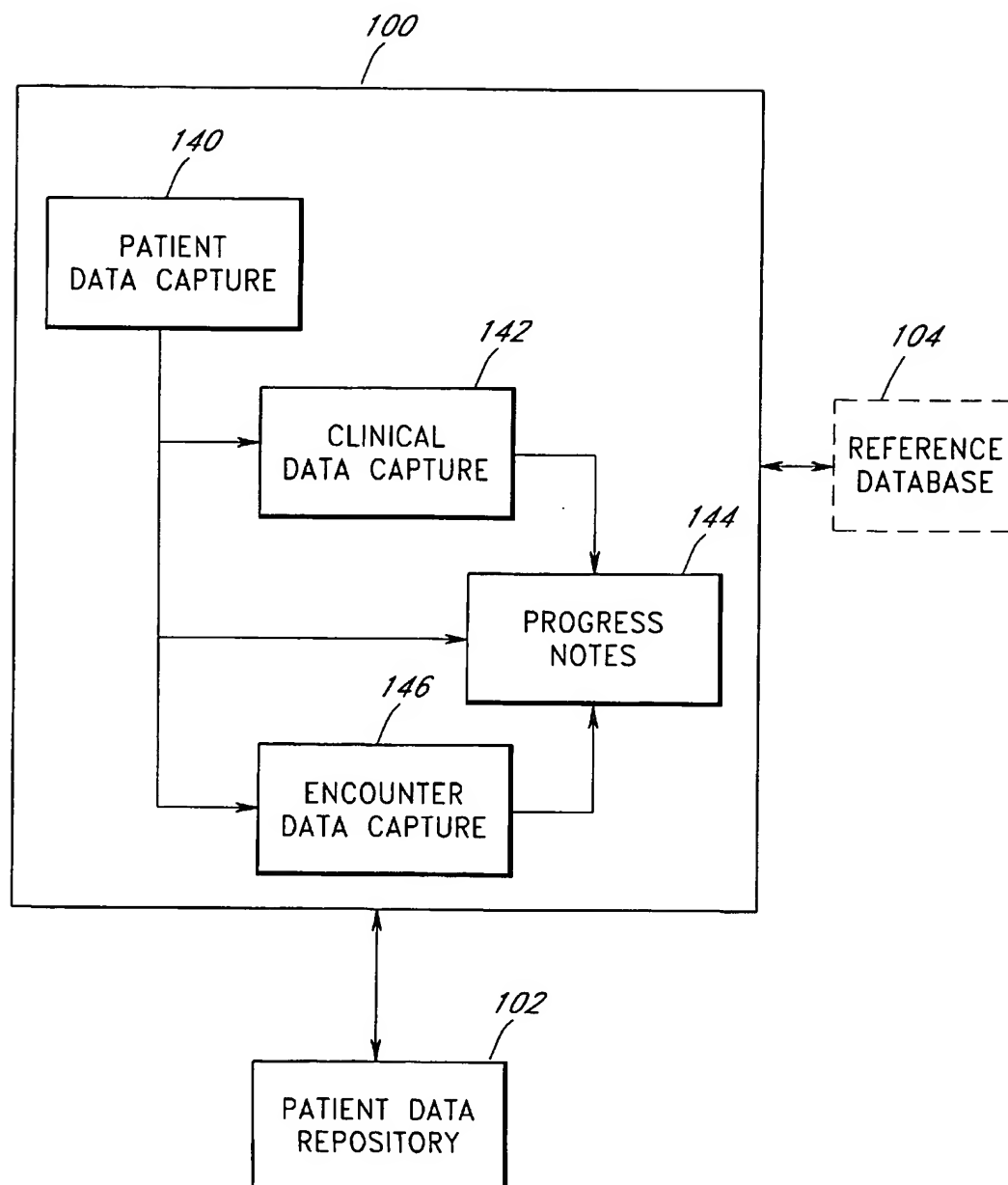
Referral

☒ Provider ☐ Phonebook ☐ Other Add...

Select Remove if you would like to delete this appointment.

☐ Clear On Save Save Remove Exit

FIG. 3

**FIG. 4**

150 Dr. Phil Daley— Internal Medicine

151

152 153

192

Selected Patient
Denson, Bob W.

193 Practice Guidelines

191 Medication Date

154 Progress Notes

List All

History

Laboratory

Problem List

Clinical Data

Patient Data

Encounter Data

155

Date	Description	Reviewed
6/9/95	Progress Note	
2/14/94	Progress Note	X
10/23/92	Endoscopy Report	X
10/7/91	Discharge Summary—Addendum	X
9/26/91	History & Physical Examination	X
8/31/90	History & Physical Examination Cont.	X

156

157

158

159

New Forms:

FIG. 5

[illegible]

FIG. 6

178 Azron Ink Writer-Denson, Bob W.
File Edit Zoom Options

172
170

DAMON CLINICAL LABORATORY
3231 South Euclid Ave.
Barwyn, Illinois 60402
Leonas G. Bakaris, M.D.

BRIDGEVIEW INT. MED. CTR. 71
7217 W. 84TH STREET SA
BRIDGEVIEW, IL. 60455

54076,22005
PATIENT NAME
DRN SON, BOB
ACCESSION NO. AGE SEX TV/SOURCE
3156443 39 M
REFERRING PHYSICIAN CLIENT NO.
KARIDES 84699
ORDER STATUS COLLECTION DATE: TIME
COMPLETE 01/17/89 03:30 PM

TEST	OUTSIDE RANGE	WITHIN RANGE	UNITS	REFERENCE
CHEM 24				
GLUCOSE		88	MG/DL	70-111
CREATININE		0.9	MG/DL	0.6-1.1
BUN		13	MG/DL	6-21
BUN/CREATININE RATIO		14.4		7.4-23
SODIUM		147	MEQ/L	134-144
POTASSIUM		5.2	MEQ/L	3.5-5.1
CHLORIDE		110	MEQ/L	95-111
CO ₂ -AS BICARBONATE	23.1		MEQ/L	24-32
URIC ACID		4.2	MG/DL	2.5-6.1
BILIRUBIN, TOTAL		0.3	MG/DL	0.2-1.1
BILIRUBIN, DIRECT		0.0	MG/DL	0.0-0.1
BILIRUBIN, INDIRECT		0.1	MG/DL	0.1-1.1
TRIGLYCERIDE		49	MG/DL	10-25
CHOLESTEROL		197	MG/DL	120-200
LEIM		10.1	MG/DL	8.5-10
PHOSPHORUS		4.0	MMG/DL	2.4-4.1
ALK PHOSPHATASE, COLOR		109	U/L	25-111
LDH	258 H		U/L	85-211
SGPT		21	U/L	0-40
PBPTIN, TOTAL		23	U/L	0-50
		6.8	GM/DL	6.0-8.1

Out of Range

176

174

FIG. 7

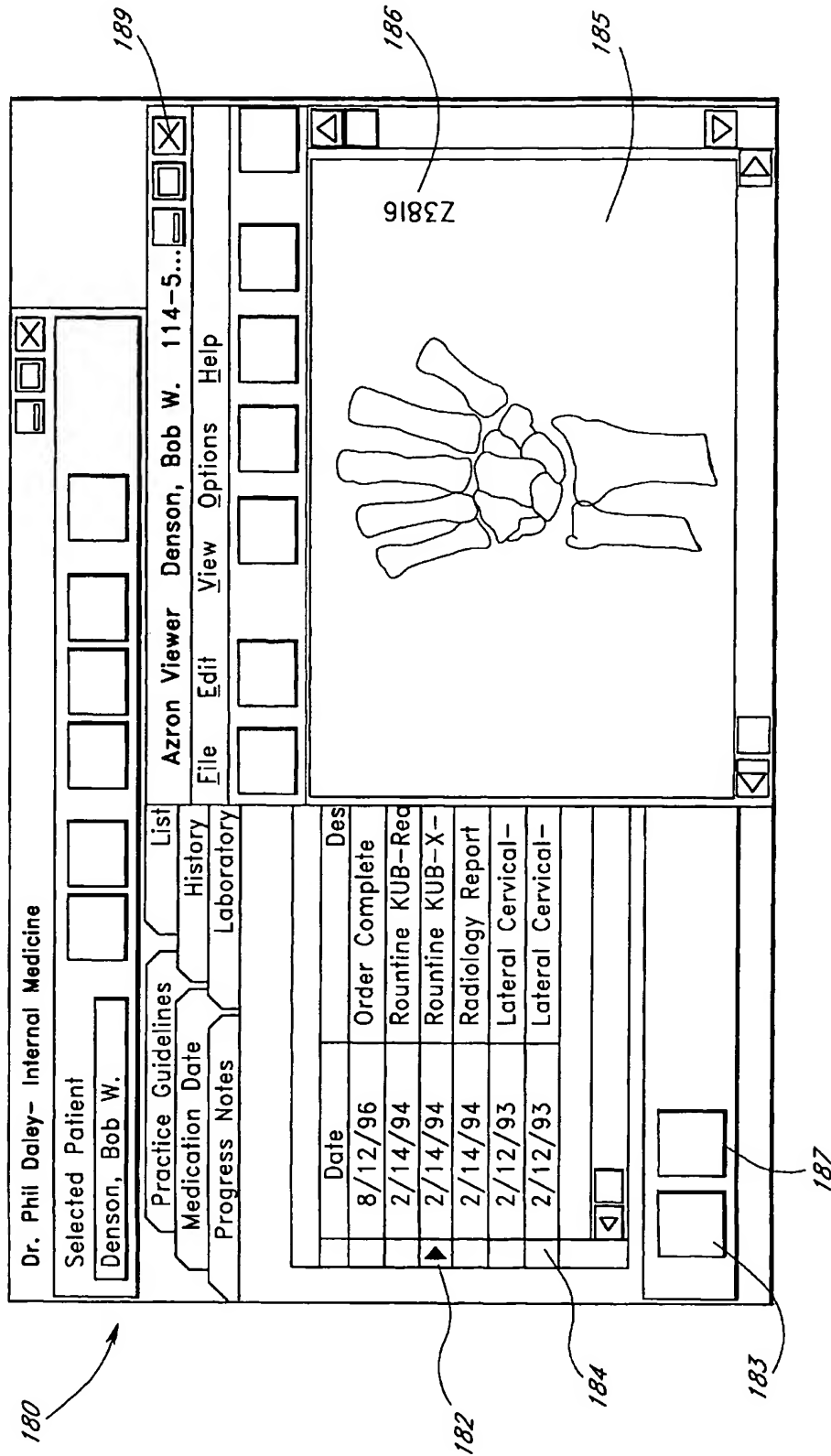
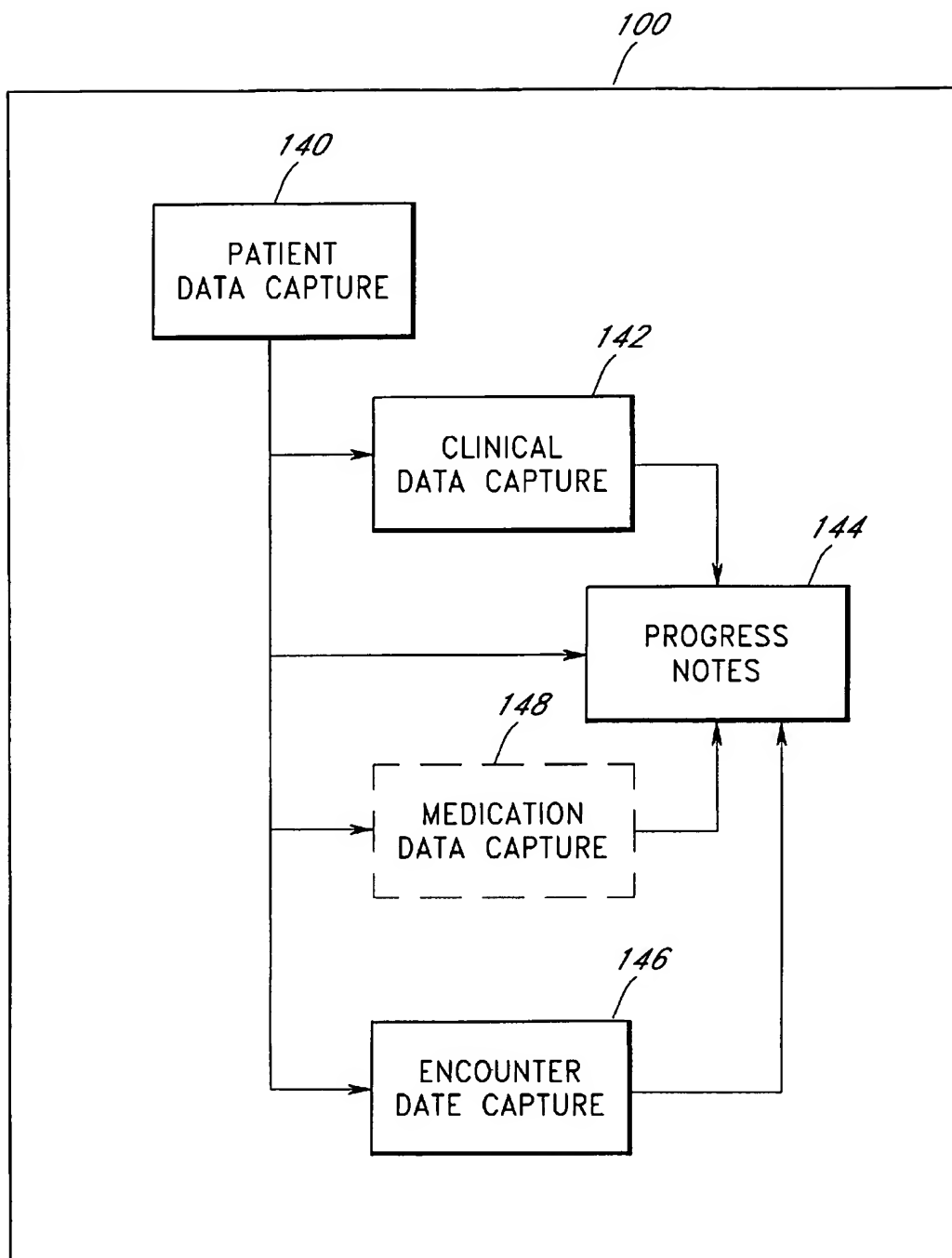
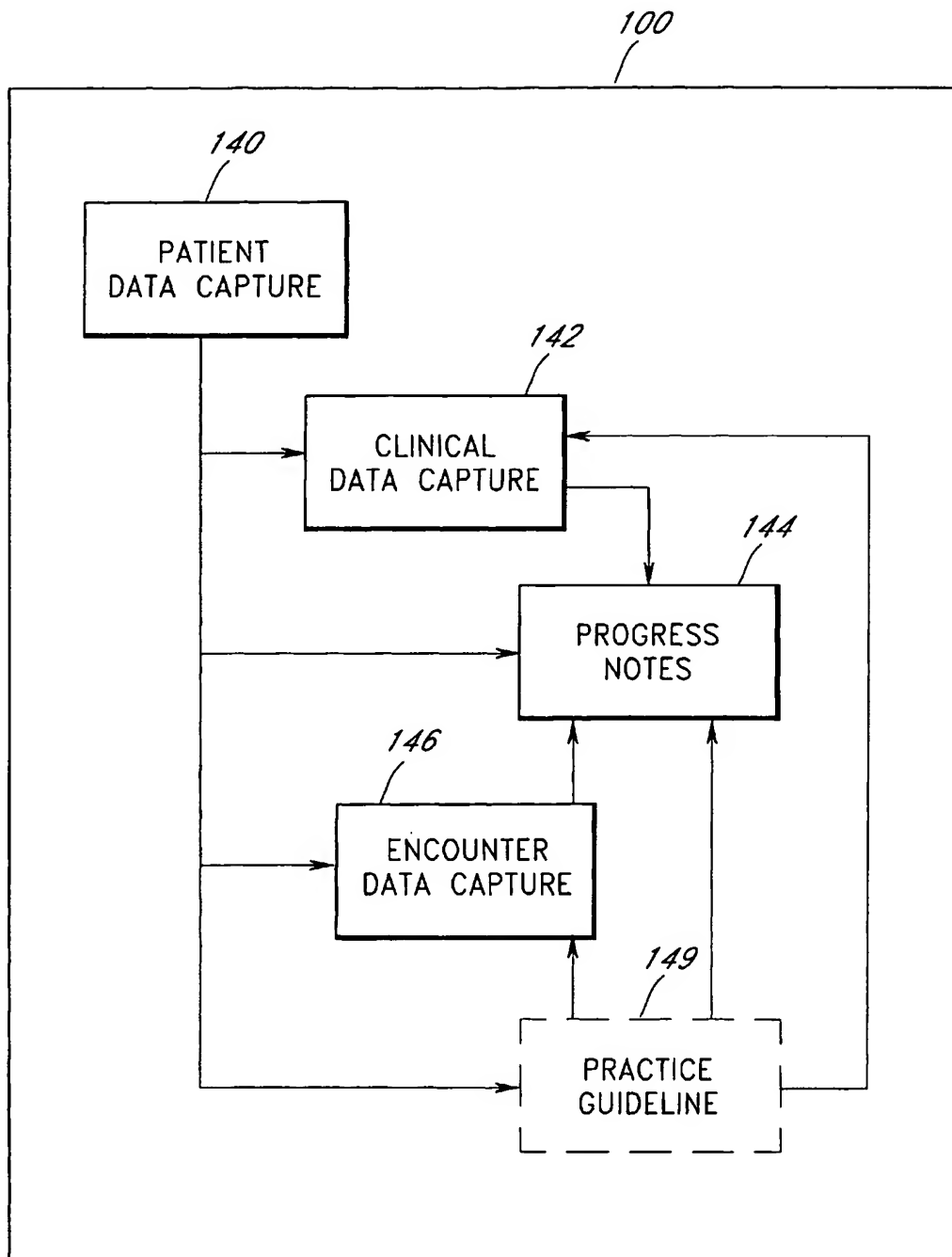
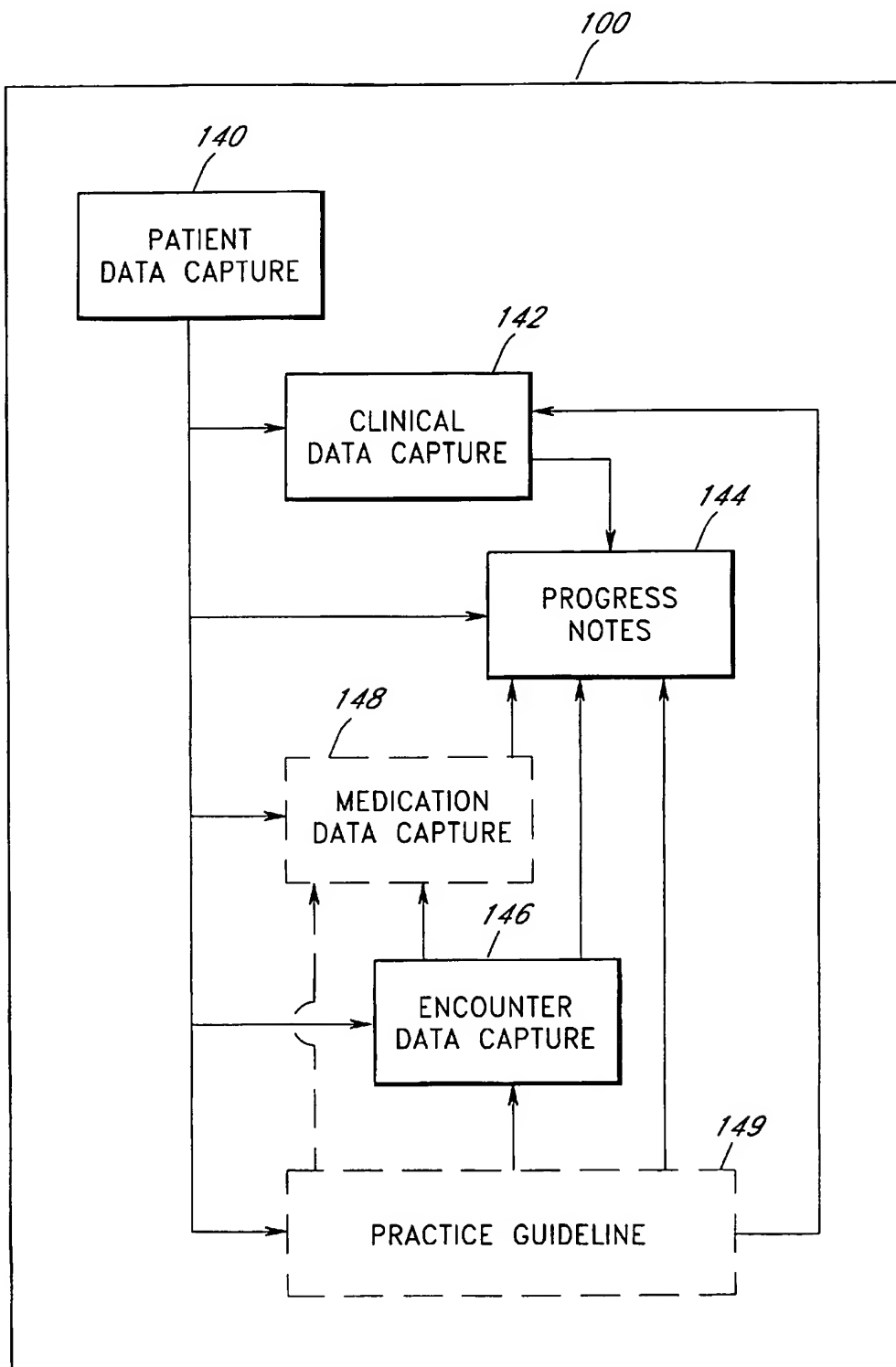


FIG. 8

**FIG. 9**

**FIG. 10**

**FIG. 11**

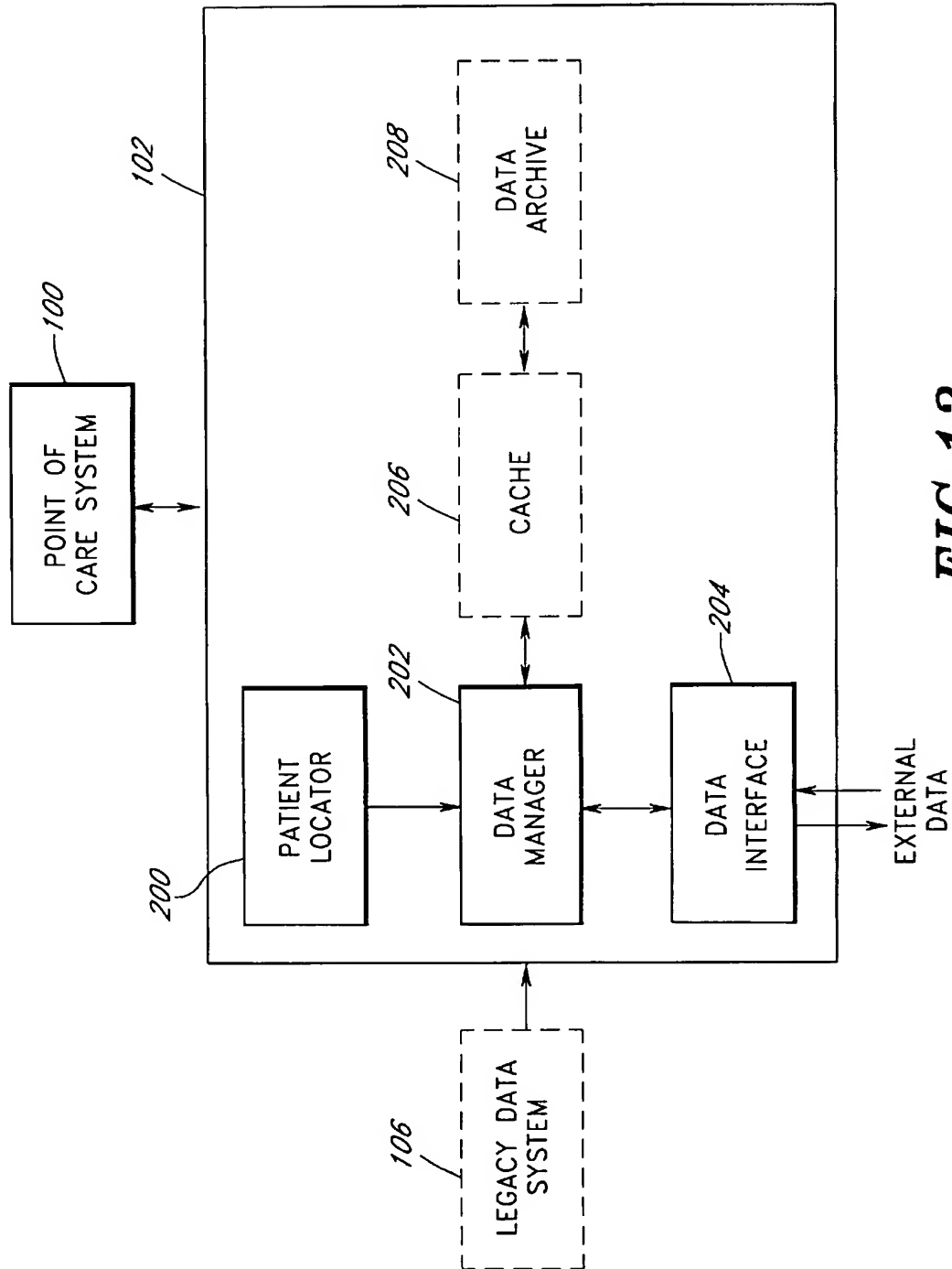
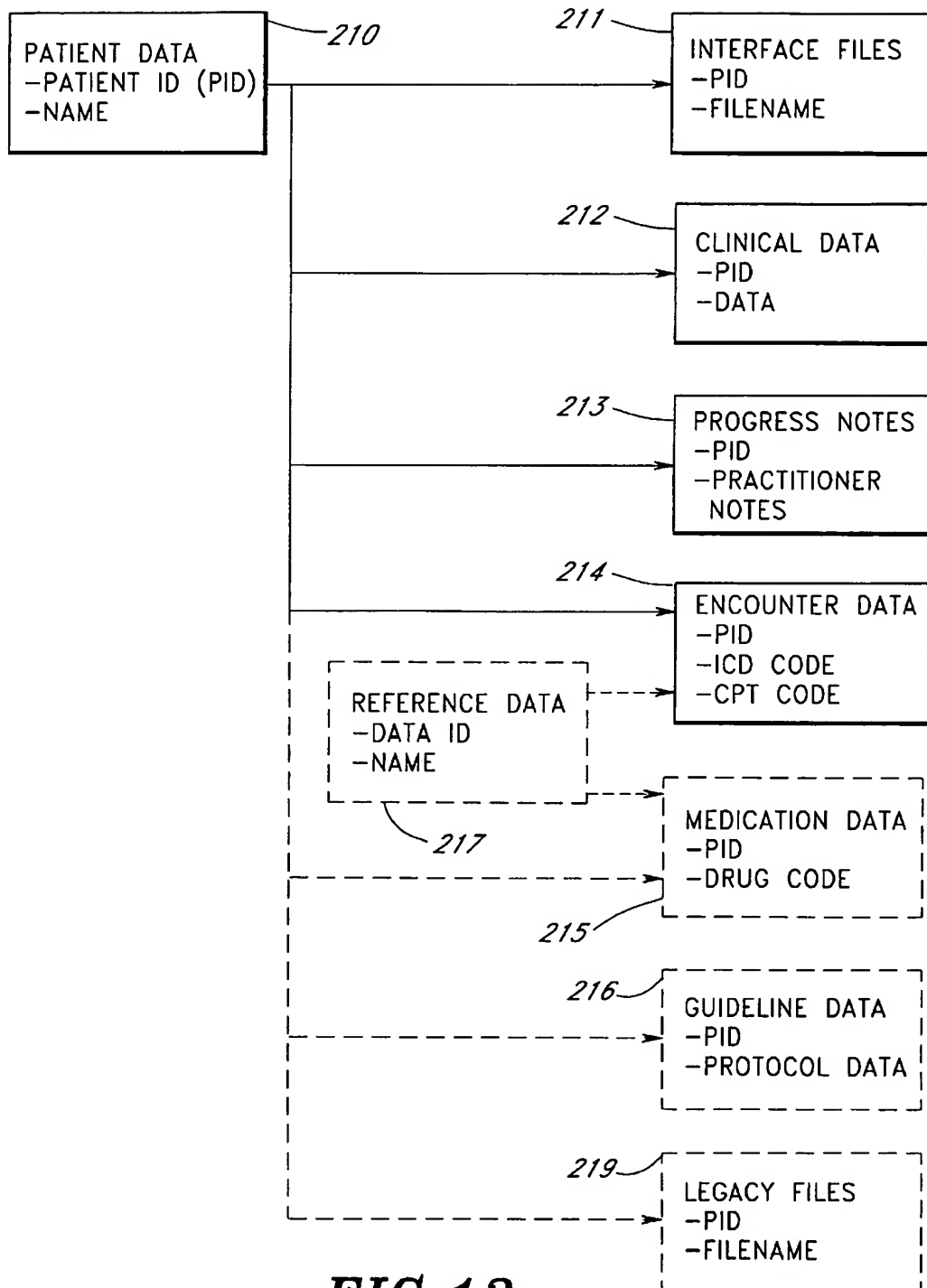
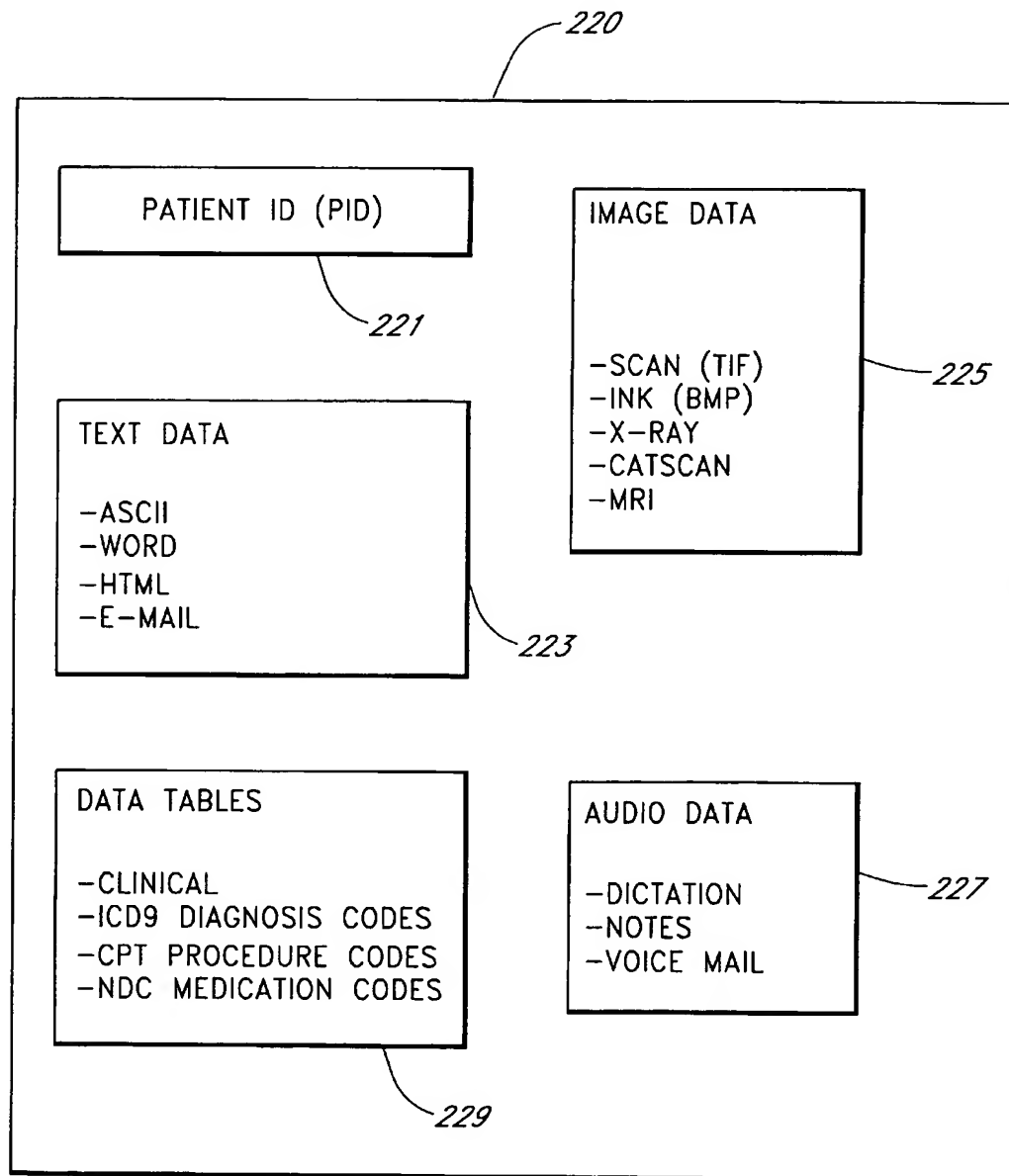
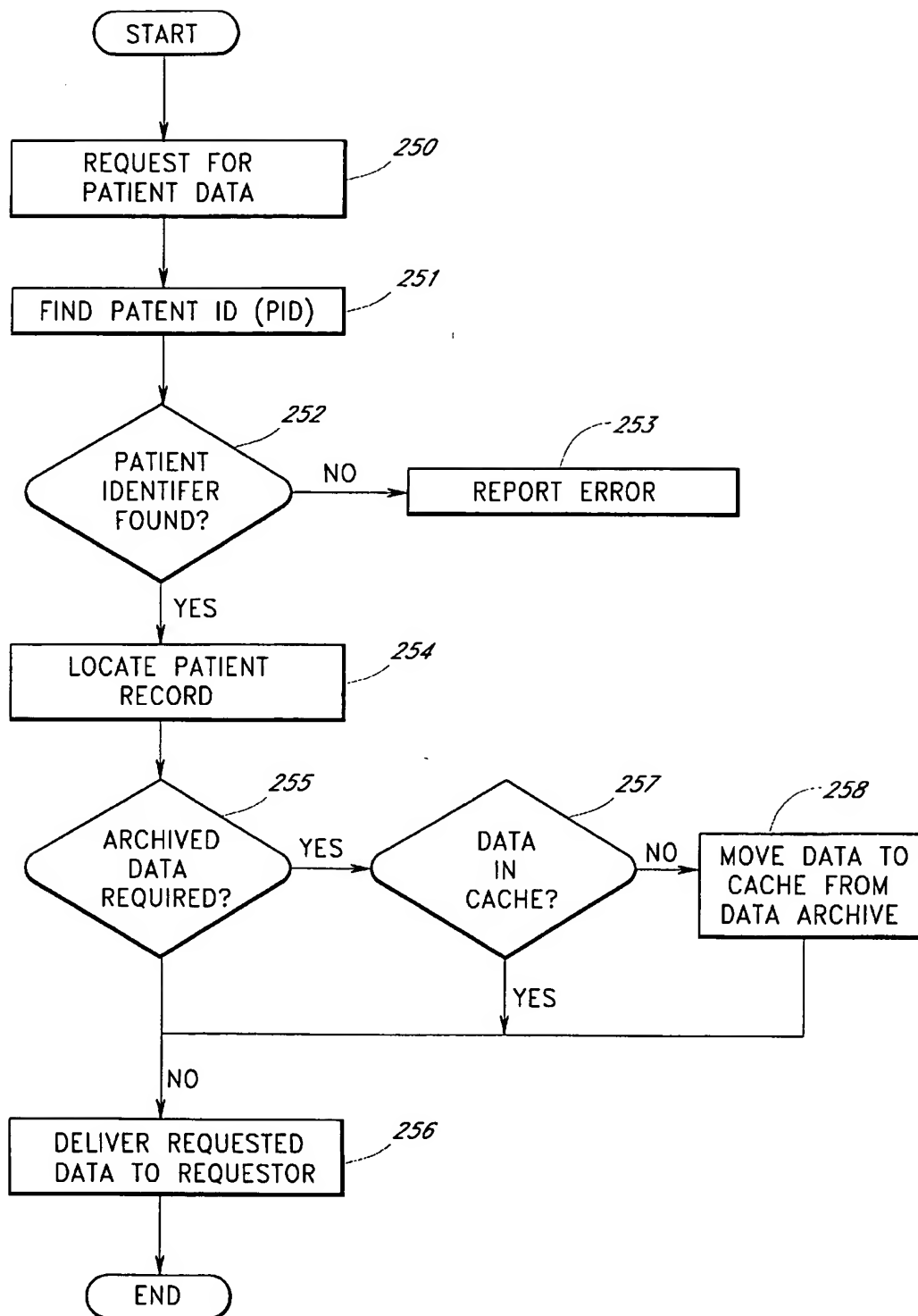
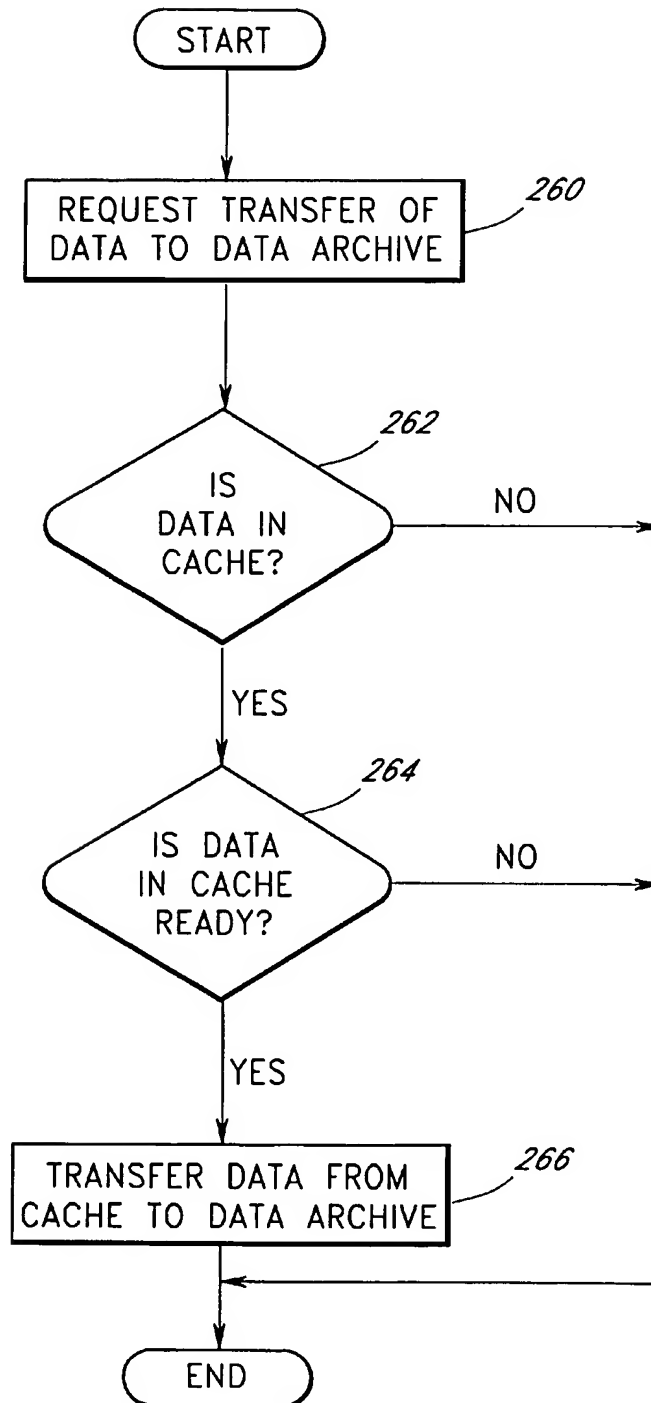


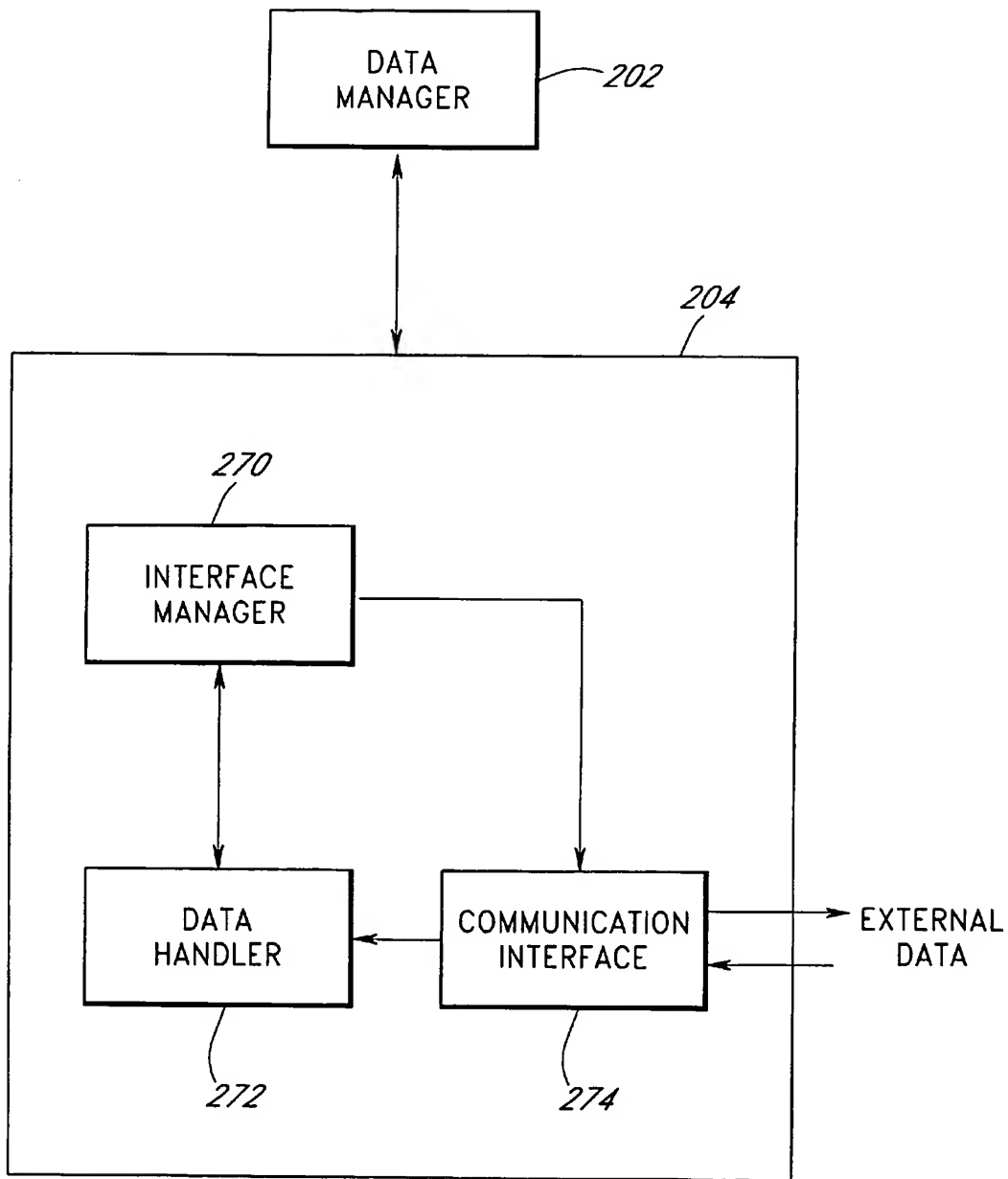
FIG. 12

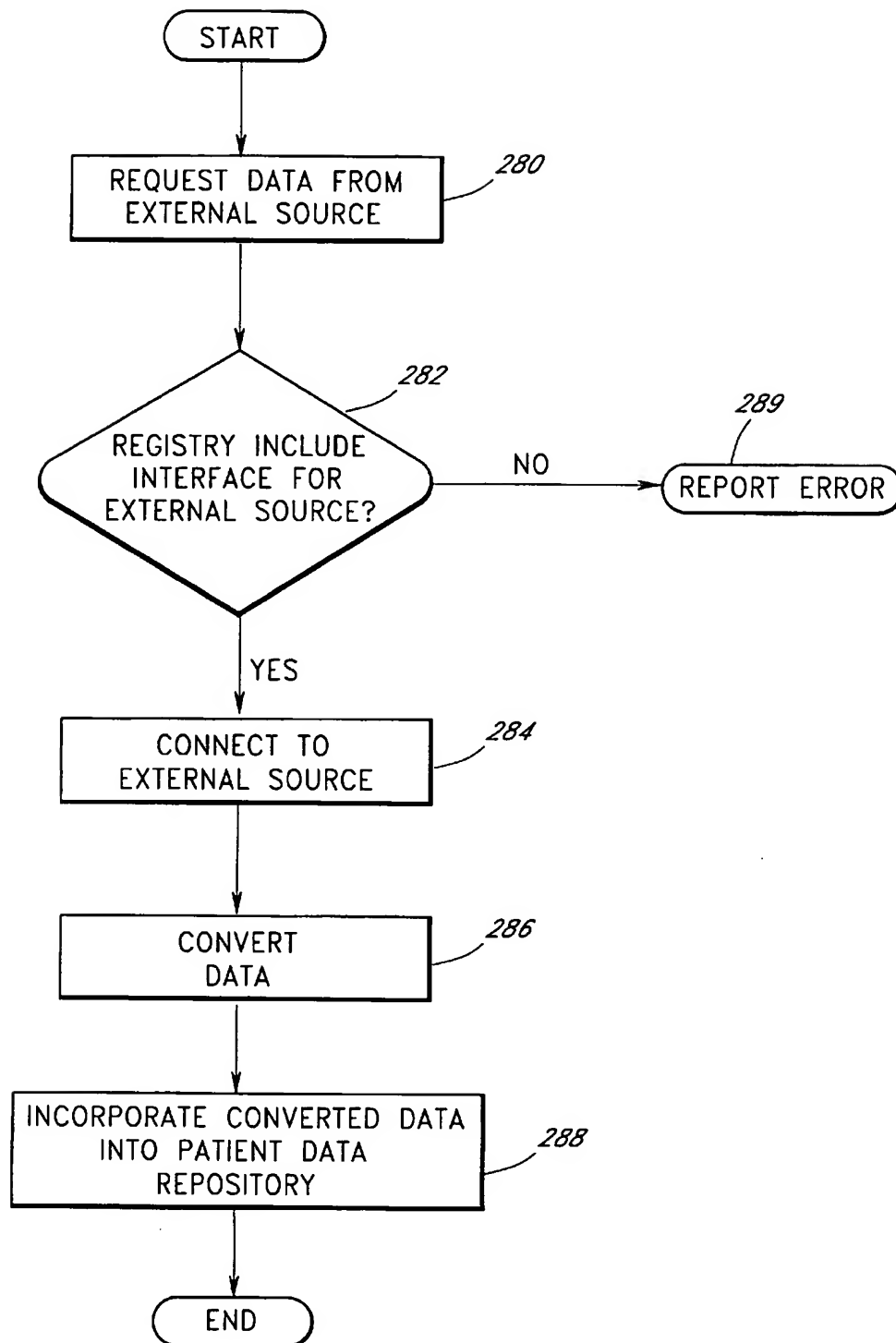
**FIG. 13**

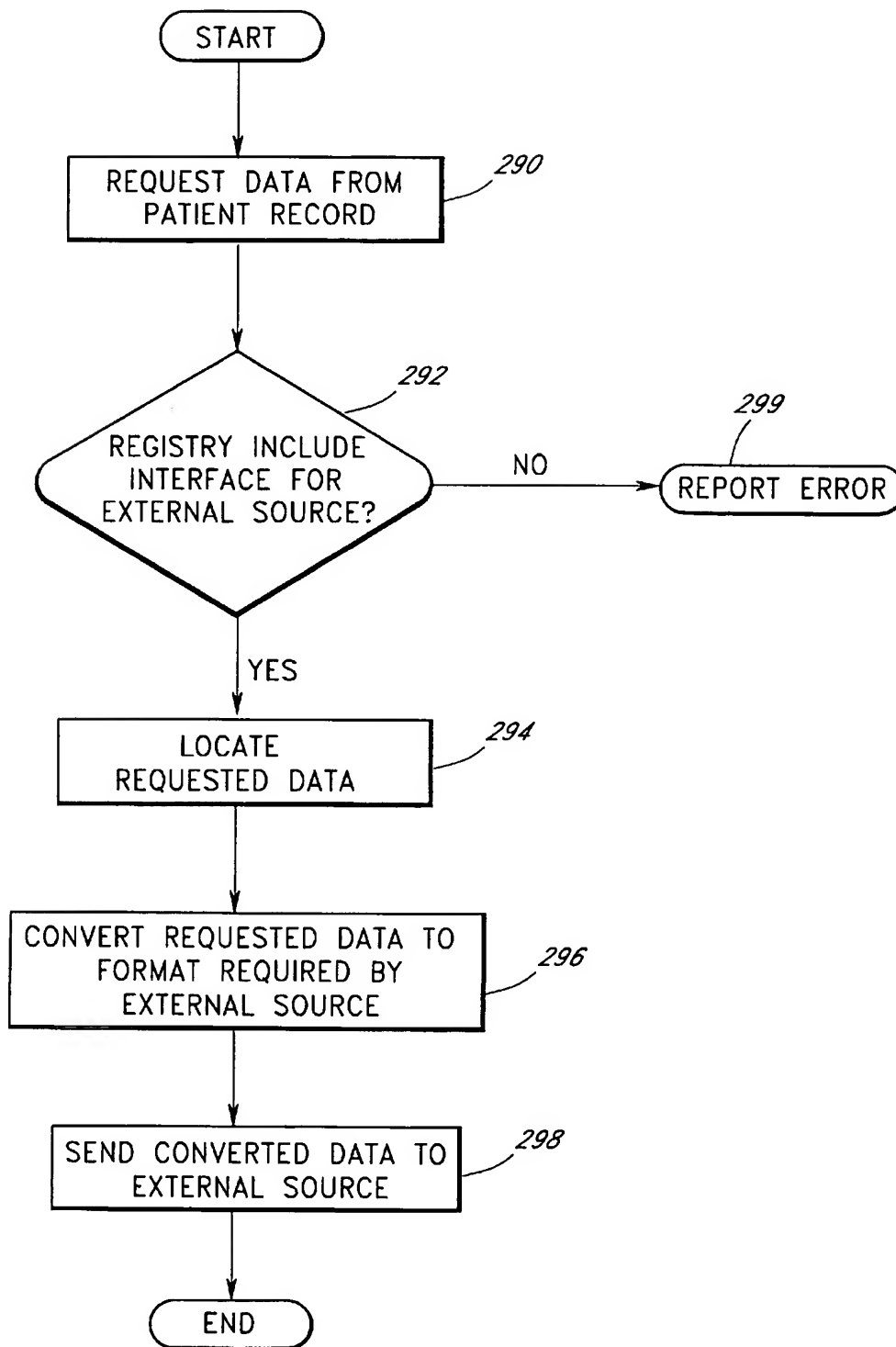
**FIG. 14**

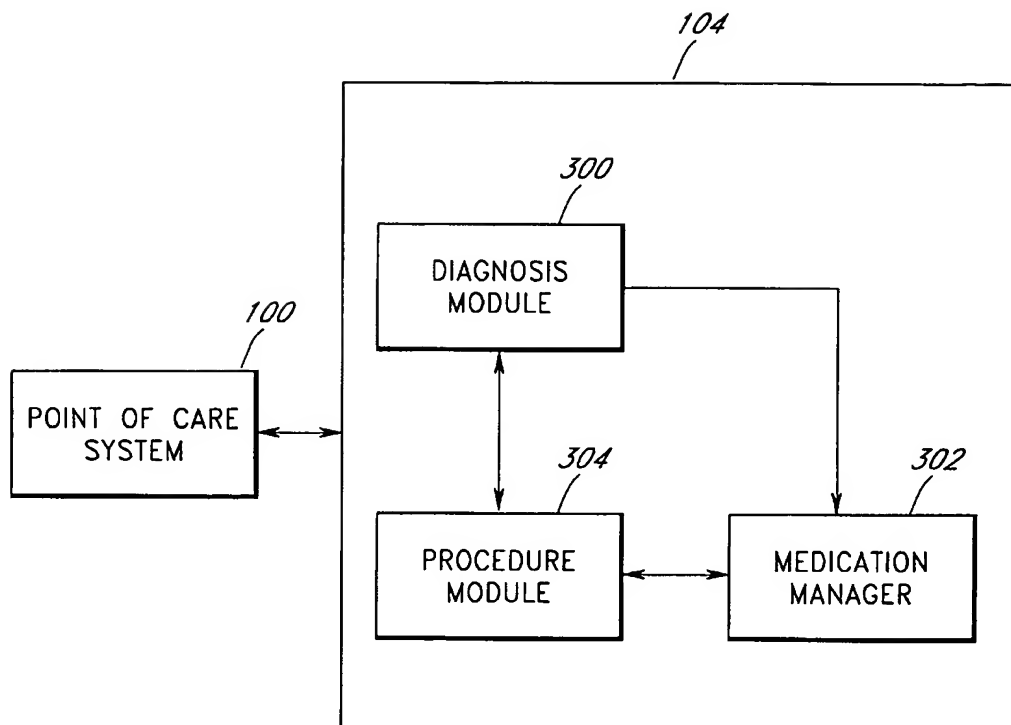
**FIG. 15A**

**FIG. 15B**

**FIG. 16**

**FIG. 17A**

**FIG. 17B**

**FIG. 18**

310

Dr. Phil Daley - Internal Medicine

192

312

Selected Patient
Denson, Bob W.

Practice Guidelines
Medication Date
Progress Notes

List All
History
Laboratory

Problem List
Clinical Data

Patient Data
Encounter Data

Laboratory			
Date	Description	Reviewed	
4/9/94	CBC		
4/8/94	Slide	X	
1/29/91	SED Rate, SMAC, CBC, Wintrobe-Allied	X	
1/17/89	Chem24, Urinalysis	X	
6/9/88	Cholesterol	X	

New Forms:

FIG. 19

332 Patient Encounter for Denson, Bob W.

330 Complete Diagnosis List by Section
Respiratory System

Sort By ☐ Code ☒ Description

Code	Description
477.0	ALLERGIC RHINITIS DUE TO POLLEN
477.9	ALLERGIC RHINITIS, CAUSE
501	ASBESTOSIS
493	ASTHMA
493.9	ASTHMA, UNSPECIFIED
493.91	ASTHMA, UNSPECIFIED TYPE, WITH
493.90	ASTHMA, UNSPECIFIED TYPE,
482.9	BACTERIAL PNEUMONIA,
495.1	BAGASSOSIS
5.1	BOTULISM
494	BRONCHIECTASIS
506.0	BRONCHITIS AND PNEUMONITIS DUE
490	BRONCHITIS, NOT SPECIFIED AS

334

333 Complete Procedure List by Section
Medicine

Sort By ☐ Code ☒ Description

Code	Description
95823	ACTIVATION EEG
97531	ADDED KINETIC THERAPY
94642	AEROSOL INHALATION TREATMENT
94665	AEROSOL OR VAPOR INHALATIONS
94664	AEROSOL OR VAPOR INHALATIONS
94640	AIRWAY INHALATION TREATMENT
95199	ALLERGY IMMUNOLOGY SERVICES
95044	ALLERGY PATCH TESTS
95028	ALLERGY SKIN TESTS
95004	ALLERGY SKIN TESTS
95024	ALLERGY SKIN TESTS
93788	AMBULATORY BP ANALYSIS
93784	AMBULATORY BP MONITORING

335

336 Selected Diagnoses

493 ASTHMA

Add Remove Clear

337

338 Selected Procedures

94642 AEROSOL INHALATION TREATMENT

Add Remove Clear

339

336

FIG. 20

Azron Medication Manager
File Edit Help

Patient Profile
Patient: Denson, Bob W. Select...
Drug Allergies: PENICILLIN
☒ Factor in Allergens Allergies...

Search Profile
Group: All Group...
Drug: ampi Keyboard..
NDC: Keypad...

Drugs Available For Profile:

Drug Name	Drug NDC
AMPICILLIN	004054089
AMPICILLIN	545691719
AMPICILLIN	545692906
AMPICILLIN	545695002
AMPICILLIN	000157992
AMPICILLIN	558290610

Add Remove Remove All

Drug Profile:
VENTOLIN,001730351
AMPICILLIN,004054089

Drug Medication History:

Start	End	Medication	Prescribe
2/14/94	2/28/94	VENTOLIN	4/9/94

Include: All current and all expired drugs.

Diagnosis History:

Date	Diagnosis
1/12/94	NO DIAGNOSIS FOR ENCOUNTER
10/23/92	COLOSTOMY AND ENTEROSTOMY
10/7/91	ANXIETY STATE, UNSPECIFIED

Results... Prescribe... Clear

Adverseor allergic drug interaction occurs with the current Drug Profile.
Exit

350 353 351 352 354 355 356 357 358 359 360

FIG. 21

361

364

362

363

365

366

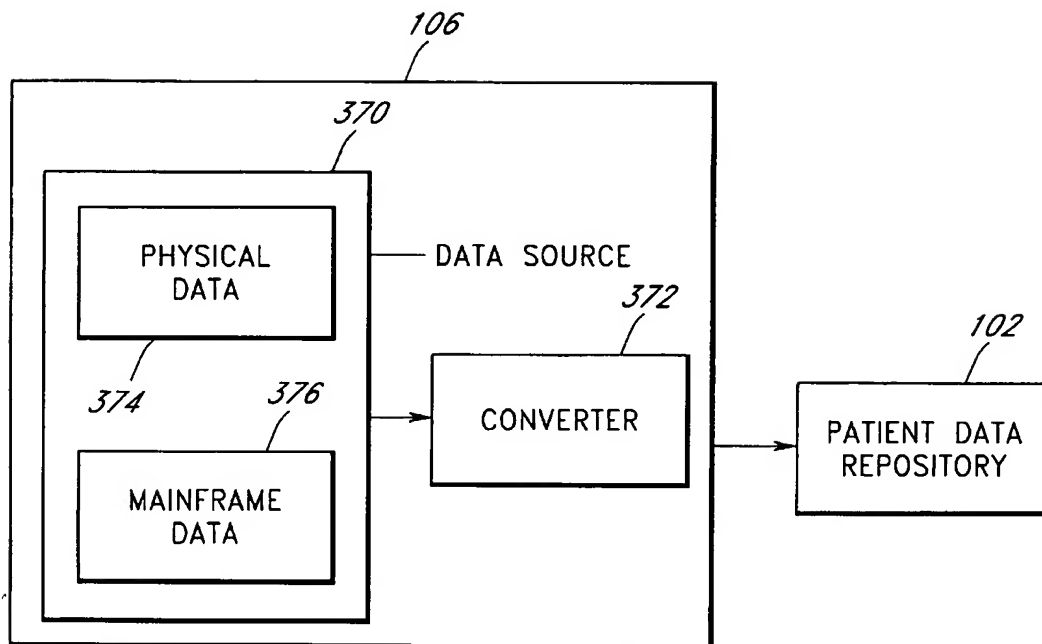
Interaction Results

Patient: Drug Profile:

Allergens:

DRUG-ALLERGY INTERACTION:
Adverse Effect: CROSS-ALLERGENICITY REPORTED BETWEEN PENICILLINS.
CEPHALOSPORINS, AND RELATED AGENTS.
Reaction
ANAPHYLAXIS: ASTHMA: SKIN RASH
Probable Mechanism: Evidence suggests that some penicillin-sensitive patients may acquire cephalosporin hypersensitivity rather than cross-reactivity between penicillins and cephalosporins because antibodies to penicillins were not present (Anderson & Adkinson, 1987; Petz, 1978).
Summary:
Penicillin-sensitive patients have a higher frequency of hypersensitivity

FIG. 22

**FIG. 23**

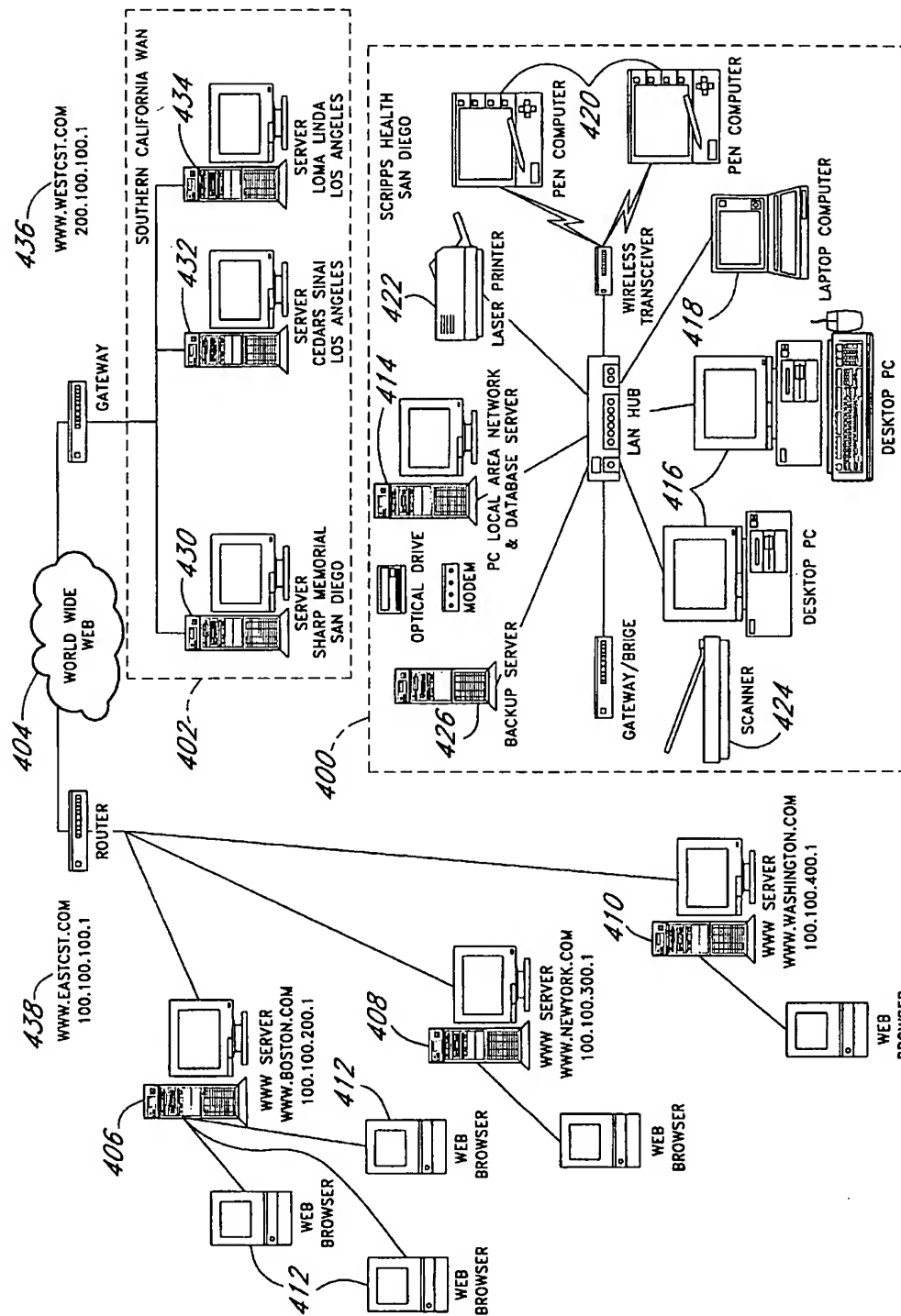


FIG. 24

ELECTRONIC MEDICAL RECORDS SYSTEM

FIELD OF THE INVENTION

The present invention relates to electronic healthcare systems, and more particularly, to a system for storage and retrieval of electronic medical records in a computer environment, such as a local or wide area network including portable computers.

DESCRIPTION OF RELATED TECHNOLOGY

Healthcare providers, such as physicians, create large volumes of patient information during the course of their business at healthcare facilities, such as hospitals, clinics, laboratories and medical offices. For example, when a patient visits a physician for the first time, the physician generally creates a patient file including the patient's medical history, current treatments, medications, insurance and other pertinent information. This file generally includes the results of patient visits, including laboratory test results, the physician's diagnosis, medications prescribed and treatments administered. During the course of the patient relationship, the physician supplements the file to update the patient's medical history. When the physician refers a patient for treatment, tests or consultation, the referred physician, hospital, clinic or laboratory typically creates and updates similar files for the patient. These files may also include the patient's billing, payment and scheduling records.

Healthcare providers can use electronic data processing to automate the creation, use and maintenance of their patient records. For example, in U.S. Pat. No. 5,277,188, assigned to New England Medical Center Hospitals, Inc., Selker discloses a clinical information reporting system having an electronic database including electrocardiograph related patient data. Similarly, Schneiderman discloses a computer system for recording electrocardiograph and/or chest x-ray test results for a database of patients in U.S. Pat. No. 5,099,424. In U.S. Pat. No. 4,315,309, Coli discloses a patient report generating system for receiving, storing and reporting medical test data for a patient population. Mitchell, in U.S. Pat. No. 3,872,448, likewise discloses a system for automatically handling and processing hospital data, such as patient information and pathological test information using a central processing apparatus. In U.S. Pat. No. 5,065,315, Garcia discloses a computerized scheduling and reporting system for managing information pertinent to a patient's stay in the hospital. However, these electronic data processing systems can not handle patient data in the wide variety of data formats typically produced by healthcare providers, such as physicians, laboratories, clinics and hospitals.

Physicians often use paper based forms and charts to document their observations and diagnosis. Laboratories also produce patient data in numerous forms, from x-ray and magnetic resonance images to blood test concentrations and electrocardiograph data. Clinics and hospitals may use a combination of paper based charts and electronic data for patient records. The same patient data may exist in remote patient files located at clinics, hospitals, laboratories and physicians' offices. Similarly, patient files at one healthcare provider typically have different information than patient files at another healthcare provider. When in use, patient files are generally not available to other healthcare providers. In addition, at the time of creation, patient data is generally not available for use by remotely located healthcare providers. Moreover, relationships among specific patient data, such as

abnormal laboratory test results, prescribed medications to address the abnormality, and specific treatments administered by the physician, may not be apparent within a patient file.

In the current environment, specific patient data is difficult to access when needed for analysis. The creation of patient data in remote locations exacerbates this problem. In addition, the wide variety of data formats for patient data hinders electronic processing and maintenance of patient files. Moreover, the use of a patient's file by one healthcare provider can preclude its simultaneous use by another healthcare provider. Ongoing consolidation of healthcare providers into large health maintenance organizations (HMOs) and preferred provider organizations (PPOs) create issues in the transfer and maintenance of patient data in large enterprises having numerous remote locations. Under these circumstances, healthcare providers have difficulty providing effective treatment for their patients.

SUMMARY OF THE INVENTION

The electronic medical record (EMR) system of the present invention automates and simplifies existing methods of patient chart creation, maintenance and retrieval. In contrast to other systems, the present invention creates and maintains all patient data electronically and thus can eliminate or supplement creating and maintaining of physical data records. The EMR system finishes healthcare providers with an intuitive, easy-to-use, icon-based interface that enables them to capture and analyze patient data quickly and efficiently. Using the present invention, healthcare providers enter patient data immediately at the point of care. Thus, the EMR system captures each piece of data at its source at the time of entry to provide a complete audit trail for all patient data. In this manner, the EMR system transforms a patient chart from a static record of a few clinical interactions into a dynamic, real-time comprehensive record linked to an enterprise-wide clinical database. In addition, the EMR system of the present invention includes the capability to manage a wide variety of patient data formats, including patient data from external sources, such as laboratories and pharmacies. The EMR system can also incorporate a patient's legacy data, such as a paper chart, into the patient record as well as legacy data from mainframe computers.

The present invention likewise provides instant access to a patient's electronic medical record by authorized healthcare providers from any geographical location. Thus, the EMR system enables authorized healthcare providers to access and update patient files using wireless pen-based personal computers. To enable complete replacement of physical records, the present invention permits healthcare providers, such as physicians or nurse practitioners, to electronically annotate patient data. Thus, a healthcare provider can acknowledge reviewing patient data, provide instructions, such as prescriptions for medication to administer to a patient, and approve recommendations for treatment by other providers, all by electronically annotating a patient's record. In addition, authorized healthcare providers can access a record while other providers use the same record allowing for real-time collaboration. The availability of electronic data permits instant, sophisticated analysis of patient data. Moreover, the EMR system enables enhanced analysis of patient data by providing access to reference databases for diagnosis, procedures and medication.

One aspect of the present invention includes a medical records system, comprising a point of care system to capture patient data at a point of care and a patient data repository,

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in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system.

Another aspect of the present invention includes a medical records system comprising a point of care system to capture data in a patient record at a point of care, wherein the patient record includes a patient identifier and at least one data structure including the patient identifier and the data.

Yet another aspect of the present invention includes a medical records system comprising a point of care system to capture data at a point of care and a patient data repository, in communication with the point of care system and with external systems to store and organize the data in a patient record for access by the point of care system, wherein the patient record includes a patient identifier and at least one data structure including the patient identifier and the data.

In addition, another aspect of the present invention includes a method of using an electronic medical records system, comprising the steps of capturing patient data electronically at the point of care, organizing the patient data so as to form a patient record, filing the patient record, and retrieving the patient record to access the patient data for use in the care of a patient.

Yet another aspect of the present invention includes a method of retrieving patient data in an electronic medical records system having a patient data repository, comprising the steps of obtaining a patient identifier, locating a patient record corresponding to the patient identifier in the patient data repository, and determining the location of the patient data within the patient record.

Another aspect of the present invention includes a method of managing a patient data repository having a cache and a data archive, comprising the steps of monitoring a status of data within the cache, and moving the data to the data archive when the status exceeds a threshold.

Still another aspect of the present invention includes a method of communicating with an external source having an interface to an electronic medical records system, comprising the steps of finding an interface for the external source, connecting to the external source using the interface, and converting patient data for transfer between the external source and the electronic medical records system.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram illustrating the electronic medical record (EMR) system architecture of the present invention.

FIG. 2 is a flowchart illustrating the process flow of the EMR system of the present invention.

FIG. 3 shows an example of a graphical user interface of the EMR system useful for the scheduling of a patient appointment as shown in FIG. 2.

FIG. 4 is a block diagram illustrating the structure of the point of care system of FIG. 1.

FIG. 5 shows an example of a graphical user interface of the point of care system of FIG. 4.

FIG. 6 shows an example of a new form window of the point of care system of FIG. 4.

FIG. 7 shows an example of an annotate window of the point of care system of FIG. 4.

FIG. 8 shows an example of a viewer window displaying an image of patient data of the point of care system of FIG. 4.

FIG. 9 is a block diagram illustrating the structure of a medication data capture in the point of care system of FIG. 4.

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FIG. 10 is a block diagram illustrating the structure of a practice guideline in the point of care system of FIG. 4.

FIG. 11 is a block diagram illustrating the structure of the medication data capture and the practice guideline in the point of care system of FIG. 4.

FIG. 12 is a block diagram illustrating the structure of the patient data repository of FIG. 1.

FIG. 13 is a block diagram illustrating the structure of a patient record within the patient data repository of FIG. 12.

FIG. 14 is an example of the patient record of FIG. 13.

FIG. 15a is a flowchart illustrating the process flow of the patient data repository of FIG. 12.

FIG. 15b is a flowchart illustrating the process for a transfer of data from a cache to a data archive in the patient data repository of FIG. 12.

FIG. 16 is a block diagram illustrating the structure of the data interface of FIG. 12.

FIG. 17a is a flowchart illustrating the process flow of the data interface of FIG. 16 when receiving patient data from an external source.

FIG. 17b is a flowchart illustrating the process flow of the data interface of FIG. 16 when transmitting patient data to an external source.

FIG. 18 is a block diagram illustrating the structure of the reference database of FIG. 1.

FIG. 19 shows an example of a graphical user interface of the point of care system of FIG. 4 having a reference access button and a medication manager button.

FIG. 20 shows an example of a graphical user interface for the diagnosis module and the procedure module of the reference database of FIG. 18.

FIG. 21 shows an example of a graphical user interface for the medication manager of the reference database of FIG. 18.

FIG. 22 shows an example of a medication interaction window of the medication manager of FIG. 21.

FIG. 23 is a block diagram illustrating the structure of the legacy data system of FIG. 1.

FIG. 24 is an example of a typical configuration for the electronic medical records system of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following detailed description of the preferred embodiments presents a description of certain specific embodiments to assist in understanding the claims. However, one may practice the present invention in a multitude of different embodiments as defined and covered by the claims.

For convenience, the description comprises three sections: EMR System Architecture and Overview, EMR System Configurations and Summary. The first section provides an overview of the EMR system architecture, the following section describes EMR system applications and preferred embodiments for practicing the EMR system of the present invention, and the remaining section summarizes advantageous features of the present invention.

I. EMR System Architecture and Overview

FIG. 1 illustrates the architecture of the EMR system. Healthcare providers, such as physicians, at hospitals, laboratories and clinics, generally capture and access patient data using a point of care system 100 that communicates with a

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patient data repository 102. Patient data, such as vital signs, x-ray images and laboratory results, resides in the patient data repository 102. The patient data repository 102 also communicates with external sources to obtain patient data, such as laboratory test results and x-ray images, and to transfer patient information, such as prescriptions for medication, from the EMR system to other healthcare providers. The point of care system 100 captures patient data in real-time at the point of care, that is, where healthcare providers interact with their patients. For example, physicians can use a point of care system 100 to enter, access, process, analyze and annotate data from patient records in real-time at the point of care. Thus, using the point of care system 100, a physician, who has many patients in a hospital, can visit each patient in their room, access their electronic patient record there, enter results of the current examination, evaluate their medical history, electronically annotate their x-rays images and prescribe medications and treatments instantaneously as the point of care system 100 captures and organizes patient data into the patient record stored in the patient data repository 102. The point of care system 100 may likewise communicate with a reference database 104 to assist a healthcare provider in making diagnoses, prescribing medications and administering treatments. Moreover, the patient data repository 102 may also communicate with a legacy data system 106 to access pertinent patient data in paper files and mainframe electronic databases.

Referring now to FIG. 2, a flowchart illustrates the operation of the EMR system. For example, a patient having a complaint contacts a healthcare provider 110, such as a physician, to schedule an appointment. The EMR system obtains the patient record 111 from the patient data repository 102 (FIG. 1) prior to the scheduled appointment. The EMR system is also capable of handling patients on a walk-in basis by scheduling an appointment and requesting the patient's record immediately thereafter. The EMR system updates the patient record 112 to include the complaint and other information pertinent to the appointment, such as insurance information. A healthcare provider, such as a physician, examines the patient 113 using the point of care system 100 (FIG. 1) to make a diagnosis and to treat the patient's condition. As determined at 114, if a diagnosis is not possible on the basis of this examination, the physician may need to obtain additional clinical data 115, such as laboratory tests and x-rays. When available, the physician uses the point of care system 100 (FIG. 1) to evaluate the results 116 and to examine the patient 113 again in light of the results. Upon making a diagnosis, the physician may need to prescribe medications 117 for the patient's condition. Similarly, the physician may need to administer a treatment 118 to address the patient's condition. At the conclusion of the patient's visit, the EMR system files the patient's record 119 in the patient data repository 102 (FIG. 1) for future reference.

In a preferred embodiment, the EMR system includes graphical user interfaces to access system functions. For example, as shown in FIG. 3, a chart puller window 120 enables a healthcare provider to schedule a patient appointment using its point and click interface. To schedule an appointment, a healthcare provider activates the select button 121 with a pointing device, such as a mouse or electronic pen, to obtain a list of patients. The healthcare provider then scans the list to select the name of the appropriate patient using a pointing device. The EMR system places the name of the selected patient in the patient box 123. Similarly, the healthcare provider uses the up/down buttons 125 to select

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an appointment date and an appointment time. An adjacent box, such as the date box 126, displays the selected date and time. Lastly, the healthcare provider enters a textual description of the patient's complaint in a reason box 127. Note that the healthcare provider can review prior or future scheduled appointments by clicking on the appointments button 128. Similarly, the healthcare provider can track referrals by entering the identity of persons who referred this patient to their care in the referral box 129.

Referring now to FIG. 4, a block diagram illustrates the structure of the point of care system 100. The point of care system 100 includes the following modules: a patient data capture 140, a clinical data capture 142, progress notes 144 and an encounter data capture 146. During a patient visit, the healthcare provider (not shown) can enter, review and annotate patient information, such as family history, appointments, current medications and complaints, using the patient data capture 140. The healthcare provider can likewise enter, review and annotate clinical data obtained during the visit, such as body temperature and blood pressure, using the clinical data capture 142. Similarly, the healthcare provider can enter laboratory data for patients with the clinical data capture 142. The clinical data capture 142 communicates with the patient data capture 140 to assist in identifying needs for further clinical data. For example, a family history of high blood pressure may indicate a need to obtain the patient's blood pressure during the visit. The patient data capture 140 also communicates with the encounter data capture 146, where a healthcare provider can enter, review and annotate data regarding diagnoses and procedures administered to the patient. Moreover, the healthcare provider can use the progress notes 144 to summarize details of the patient's condition and to review the patient's progress over time. Thus, the progress notes 144 communicates with the patient data capture 140, the clinical data capture 142 and the encounter data capture 146.

Referring now to FIG. 5, in a preferred embodiment, the point of care system 100 (FIG. 1) includes a graphical user interface having a patient chart window 150 to capture patient information. The point of care system 100 presents a patient record graphically using a tabbed layout to organize patient data. The patient chart window 150 includes tabs for patient data 151, clinical data 152, encounter data 153 and progress notes 154. Pointing and clicking on a tab on the patient chart window 150 opens a folder window 155 where a healthcare provider can enter and review patient data within the folder. For example, to activate progress notes 144 (FIG. 4), the healthcare provider selects the progress notes tab 154 to display a list of progress note data in the folder window 155. In a similar manner, to activate the patient data capture 140, the clinical data capture 142 or the encounter data capture 146, one selects the patient data tab 151, the clinical data tab 142, or the encounter data tab 153, respectively.

To enter patient data, the healthcare provider clicks on the scroll down button 156 to select a form from a list of available forms to enter patient data. This activates the new forms box 157. The provider then points and clicks on the new form button 158. For example, FIG. 6 shows a new form window 161 displaying the pediatric problem form 162 selected by the healthcare provider using the scroll down button 156 (FIG. 5). The healthcare provider fills out the pediatric problem form 162 using an input device, such as a keyboard, a mouse or an electronic pen. For example, the provider uses a keyboard to enter text "6/7/96 Stomach Ache" 164 and an electronic pen to enter initials 166 for identification. When done with patient data entry, the pro-

vider exits the form using the File Menu 168 and the point of care system 100 returns the provider to the patient chart window 150 (FIG. 5). Referring back to FIG. 5, the new form appears as the top entry of the list in the folder window 155.

Similarly, to annotate patient data, the healthcare provider first selects an item to annotate by pointing and clicking on the item in a list displayed in the folder window 155. The provider then clicks on the annotate button 159 to open the item in an annotate window 170, as shown in FIG. 7. For example, the annotate window 170 of FIG. 7 displays a blood test result 172. As before, the healthcare provider annotates the blood test result document 172 using an input device, such as a keyboard, a mouse or an electronic pen. For example, the provider uses a keyboard to enter text "Out of Range" 174 and an electronic pen to circle 176 the out of range result. When done with annotations, the provider exits the form using the File Menu 178 and the point of care system 100 returns the provider to the patient chart window 150 (FIG. 5). Note that the point of care system 100 tracks the review of patient data and identifies reviewed files with a mark 160 in the folder window 155. By annotating patient data, a healthcare provider, such as a physician, can acknowledge reviewing patient data, provide instructions, such as directions for additional tests and procedures or prescriptions for medication to administer to the patient, and approve recommendations for treatment by other healthcare providers. Lastly, as shown in FIG. 8, a healthcare provider uses the patient chart window 180 to view patient data. First, the healthcare provider selects a view item 182 by either pointing and clicking twice on the item in a list displayed in the folder window 184 or by pointing at the item in the list and pressing the view button 183. The double click opens a viewer window 185 to display the view item 182. For example, the viewer window 185 of FIG. 8 displays an x-ray 186. As before, the healthcare provider may annotate the x-ray 186 with comments and observations by clicking on the annotate button 187. The healthcare provider may likewise close the viewer window 185 by clicking on the close button 189.

Certain additional structures in the point of care system 100 (FIG. 1) will now be discussed with reference to FIGS. 9, 10 and 11. Referring now to FIG. 9, an optional medication data capture 148 supplements the structure of the point of care system 100 of FIG. 4. A medication data capture 148 allows a healthcare provider to monitor a patient's medications. The medication data capture 148 communicates with the patient data capture 140 to account for medications the patient is currently taking. The medication data capture 148 similarly communicates with the progress notes 144, where a practitioner can monitor changes in a patient's condition resulting from medication therapies. Referring now to FIG. 10, an optional practice guideline 149 supplements the structure of the point of care system of FIG. 4. The practice guideline 149 provides references for practitioners to consult regarding courses of action to obtain a diagnosis and alternative treatments for various conditions. The practice guideline 149 communicates with the patient data capture 140, the clinical data capture 142 and the encounter data capture 146 to assist the practitioner in selecting the appropriate course of action. The practice guideline 149 likewise communicates with the progress notes 144 to provide a healthcare provider with a historical context of the patient's condition and alternative treatments already attempted.

FIG. 11 shows a point of care system 100 having a medication data capture 148 and a practice guideline 149. As before, the medication data capture 148 communicates with

the patient data capture 140 and with the progress note 144. Similarly, the practice guideline 149 communicates with patient data capture 140, the clinical data capture 142, the encounter data capture 146 and the progress note 144. However, the practice guideline 149 may now communicate with the medication data capture 148 to address situations where accepted practice guidelines require a healthcare provider to prescribe and administer medications. In a preferred embodiment, the point of care system 100 includes the graphical user interface illustrated in FIG. 5. Referring back to FIG. 5, the patient chart window 150 includes tabs for medication data 191 and practice guidelines 193 that activate the medication data capture 148 and the practice guideline 149, respectively. Similarly, pressing the medication manager button 192 activates the medication data capture 148 and the practice guideline 149. A healthcare provider can enter, review and annotate patient medication data and practice guideline data as described previously.

Referring now to FIG. 12, a block diagram illustrates the structure of the patient data repository 102. The patient data repository 102 includes a patient locator 200, a data manager 202 and a data interface 204. The patient locator 200 generates a unique patient identifier (PID) 221 (FIG. 14) for each patient and creates and maintains a table having PIDs for all patients who have data in the patient data repository 102. All data records related to a patient 211, 212, 213, 214, 215, 216, 219 include and reference the patient's unique PID as shown in FIG. 13.

With reference to FIG. 13, upon creation of a patient record, the patient locator 200 creates a patient data structure 210 having the PID and the patient's name. In a preferred embodiment, the patient data structure 210 includes pointers to data structures having data within a patient record captured by the point of care system 100 and incorporated from external sources (e.g., a digital x-ray image file stored in a raster pixel format). Thus, the patient data structure 210 maintains a pointer to an interface files structure 211 having patient data transmitted from external sources. The patient data structure 210 likewise maintains pointers to a clinical data structure 212, a progress note structure 213 and an encounter data structure 214. These data structures include patient data captured by the clinical data capture 142, progress notes 144 and encounter data capture 146, respectively (FIG. 4). In another preferred embodiment, the patient data structure 210 may include pointers to data structures having data generated by the reference database 104 and transferred by the legacy data system 106. Thus, the patient data structure 210 may maintain pointers to a medication data structure 215 and a guideline data structure 216. As described above, the medication 215 and guideline 216 data structures include patient data captured by the medication data capture 148 and the practice guideline 149, respectively. In this embodiment, a reference data structure 217 may maintain pointers to the encounter data structure 214 and to the medication data structure 215 for access to reference information contained in a reference database 104. Lastly, the patient data structure 210 may maintain a pointer to a legacy files structure 219 having patient data transmitted from the legacy data system 106, such as an image of a patient chart.

FIG. 14 shows a logical view of a patient record 220 corresponding to the structure illustrated in FIG. 13. The patient record 220 includes the PID generated by the patient locator 200 (FIG. 12) in the patient data repository 102 (FIG. 1). In addition, the patient record 220 includes patient data in a variety of data types generated by healthcare providers. Thus, the patient record includes text data 223, such as

electronic mail and word processing documents from other healthcare providers, image data 225, such as scanned physical documents, x-rays and CATSCANS, and audio data 227, such as a physician's dictation and voice mail. Lastly, the patient record 220 has data tables 229, such as a physician's ICD9 diagnosis codes and CPT procedure codes. In view of the structure of a patient record 220, referring back to FIG. 12, the data manager 202 uses the PID to store and retrieve patient records. Moreover, the data interface 204 permits communication with external sources to obtain patient data, such as demographic data, laboratory test results and x-ray images, and to transfer patient information, such as prescriptions for medication, from the patient data repository 102 to external healthcare providers.

With reference to FIG. 12, the patient data repository 102 may optionally include a cache 206 for temporary storage of patient data and a data archive 208 for long term storage of patient data. In this embodiment, the data manager 202 coordinates the transfer of patient data to and from a data archive 208 into a cache 206. For example, the data manager 202 may identify patient records that a healthcare provider needs for appointments scheduled at a future time and then transfer these patient records from the data archive 208 into the cache 206 for quick access prior to the scheduled appointment. Similarly, the data manager 202 may purge from the cache 206 records of patients who have not had recent appointments and whose records are already archived. The data manager 202 likewise tracks the location and description of patient data within the data archive 208 by associating the file name of the patient data within a patient record 220 with the patient identifier 221. When possible, the data manager 202 will group data associated with a patient within the data archive 208 for rapid retrieval in a manner similar to files within a directory in an operating system. Thus, the data manager 202 assigns a directory to each patient identifier and then stores patient data within this directory.

FIG. 15a illustrates the process flow for the patient data repository 102 (FIG. 1). For example, the point of care system 100 (FIG. 1) issues a request for patient data 250. With reference to FIGS. 15a and 12, the patient locator 200 receives the request from the point of care system 100 and, at 251 attempts to find the PID for the record having the requested patient data. As determined at 252, if no PID is found, the patient locator 200 reports an error 253. At this point, the patient data repository 102 (FIG. 1) may recover from the error 253 by either restarting the process or by ending the process. Otherwise, the patient locator 200 communicates the PID to the data manager 202. The data manager 202 locates the patient record using the PID at 254. As determined at 255, in a system without cache 206 and without a data archive 208, the data manager 202 delivers the requested data 256 to the point of care system 100. In a system having a cache 206 and a data archive 208, the data manager 202 determines at 257 if the requested data exists in the cache 206. If so, the data manager 202 delivers the requested data 256 to the requester from the cache 206. Otherwise, the data manager 202 first moves the data 258 from the data archive 208 to the cache 206 and then delivers the requested data 254 to the requester from the cache 206.

In addition, FIG. 15b, in conjunction with FIG. 12, illustrates the process for transferring data from a cache 206 to a data archive 208. The data manager 202 monitors the contents of the cache 206. To improve the performance of the cache 206, the data manager 202 requests transfer 260 of data to the data archive 208 under certain conditions. For example, the data manager 202 may purge the cache 206

when data requested for storage in the cache would exceed its memory capacity. In this circumstance, the data manager 202 first transfers to the data archive 208 signed files and then data files in chronological order, i.e., oldest files first. Similarly, a healthcare provider can specify a predetermined time, such as 3 calendar days, or other selected conditions for transfer to the data archive 208. As determined at 262, if the cache 206 does not have the data to transfer, the process ends as the data manager 202 ignores the request. As determined at 264, if the data in the cache 206 is not ready for transfer, the process ends and the data manager 202 queues the request for the next transfer of data to the data archive 208. Data in the cache 206 is ready for transfer when a physician has reviewed and accepted it and when it has not been previously committed to the data archive 208. Otherwise, the data manager 202 transfers data from the cache 206 to the data archive 208 at 266.

Referring now to FIG. 16, the data interface 204 of the patient data repository 102 includes an interface manager 270, a data handler 272 and a communication interface 274. To transfer and receive patient data from external sources (not shown), the interface manager 270 communicates with a data handler 272 and a communication interface 274. In addition, the communication interface 274 communicates with the data handler 272 for conversion of received external patient data into formats recognized by the EMR system. The interface manager 270 creates and maintains an interface registry of data formats for external sources. Prior to data transfer or receipt by the EMR system, the interface manager 270 registers an interface for an external source. Upon registration of an interface, the interface manager 270 can provide the appropriate conversion routines for the data handler 272 to use for transfer of data to and receipt of data from an external source. These conversions are well understood by the relevant technologist.

FIGS. 17a and 17b illustrate the operation of the data interface 204 of the patient data repository 102 (FIG. 12). Referring now to FIG. 17a, the data manager 202 issues a request 280 for patient data from an external source. At 282, the interface manager 270 determines if the registry includes an interface for the external source, such as a laboratory or pharmacy. As determined at 282, if the registry includes an interface for the external source, the communication interface 274 connects to the external source 284 to receive patient data. The data handler 272 retrieves the appropriate conversion routine for the external source to convert data 286. In a preferred embodiment, the data handler 272 converts data from an external source into a database table for the appropriate PID. Lastly, the data manager 202 incorporates converted data 288 into the patient record. Otherwise, the interface manager 270 reports an error 289. The data manager 202 may recover from the error 289 in several ways. First, the data manager 202 may invoke a module to register an interface for the external source so as to allow the process to continue. Second, the data manager 202 may end the process at this point. Lastly, the data manager 202 may restart the process in the event the external source was specified incorrectly.

Referring now to FIG. 17b, an external source requests data 290 from a patient record. As described above, the interface manager 270 determines at 292 if the registry includes an interface for the external source. As determined at 292, if the registry includes an interface for the external source, the data manager 202 locates the requested data at 294 and the data handler 272 converts requested data at 296 to the format required by the external source. The communication interface 274 then sends the converted data to the

external source at 298. For example, the patient data repository 102 may transmit a physician's prescription for medication to a hospital or pharmacy. If the registry includes no interface for the external source, the interface manager 270 reports an error 299. Similarly, as discussed above for the process flow of FIG. 17a, the interface manager 270 may recover from the error 299 by restarting the process, ending the process or invoking a module to register the external source to allow the process to continue.

Referring now to FIG. 18, a block diagram illustrates the structure of the optional reference database 104 (FIG. 1). The reference database 104 includes a diagnosis module 300, a medication manager 302 and a procedure module 304. A healthcare provider can use the reference database 104 for assistance in diagnosing a patient's disease, prescribing medications and ordering supplemental procedures to treat the disease. The diagnosis module 300 communicates with a medication manager 302 to obtain information on medications indicated by a diagnosis. The medication manager 302 provides information on medications, such as proper dosages, allergies, contraindications, adverse interactions with other medications, and side effects. The diagnosis module 300 likewise communicates with a procedure module 304 to obtain information on the proper administration of procedures indicated by a diagnosis. The procedure module 304 provides information on procedures for treatment as indicated by the diagnosis. In many instances, the medication manager 302 communicates with the procedure module 304 regarding the administration of various medications.

In a preferred embodiment, the point of care system 100 provides access to the reference database 104 through a graphical user interface having a patient chart window 310 shown in FIG. 19. A healthcare provider accesses the diagnosis module 300 and the procedure module 304 by pointing and clicking on a reference access button 312.

As shown in FIG. 20, the reference access button 312 produces a reference window 330 including the graphical interfaces for the diagnosis module 300 and the procedure module 304. For example, to enter a diagnosis, a physician clicks on the scroll down button 331 adjacent to the system box 332 to produce a list of body systems. The physician selects the appropriate system and the diagnosis module 300 enters the selected system in the system box 332 and provides a list having specific diagnosis codes for the selected body system in the diagnosis box 334. The physician then selects the appropriate diagnosis code and clicks on the add button 336 adjacent to the diagnosis selection box 337. The diagnosis module 300 enters the selected diagnosis code to the diagnosis selection box 337. The physician may repeat the above steps to add multiple diagnosis codes to the diagnosis selection box 337. In a similar manner, a physician uses the scroll down button 331 adjacent to the topic box 333 to select the appropriate procedure topic. The procedure module 304 enters the selected procedure topic in the topic box 333 and provides a list of procedure codes in the procedure box 335. The physician now selects the appropriate procedure code and adds it to the procedure selection box 338 by clicking on the add button 336 adjacent to the procedure selection box 338. The physician may likewise repeat the above steps to add multiple procedure codes to the procedure selection box 338. The physician completes entry of diagnoses and procedures by clicking on the done button 339 to return to the patient chart window 310 of FIG. 19.

The healthcare provider similarly accesses the medication manager 302 (FIG. 18) by clicking on a medication button 192 (FIG. 19). Referring now to FIG. 21, the medication

button 314 activates a medication manager window 350. The physician can review the patient's history by viewing the medication history box 351 and the diagnosis history box 352 before prescribing any new medications. The physician can also review any patient allergies in the allergy box 353. The physician can select a medication by entering the name of the medication in the name box 354. Note that as the physician enters the root letters of a medication name, a list of medications with the root letters appears in the medication list box 355. As before, the physician selects a medication from the list by clicking on it and the medication manager 302 places the selected medication in a selection box 356. If there are no contraindications or allergies for the patient, the physician prescribes the medications listed in the selection box 356 by clicking on the prescribe button 357.

Otherwise, if a contraindication exists, a warning appears in a warning bar 358 to alert the physician. In view of the warning, the physician can investigate the effects of the medication by clicking on the results button 359. Referring now to FIG. 22, the results button produces a medication interaction window 361. A medication selection box 362 displays the medications selected and under consideration by the physician. An allergy list box 363 displays the patient's allergens. Folder tabs 364 include labels describing the medication combinations and interactions. The physician clicks on one of these folder tabs 364 to display the contents of the folder in the viewing box 365. The physician can then evaluate the information on the interaction including potential adverse patient reactions. The physician clicks on the done button 366 to return to the medication manager window 350 of FIG. 21. The physician can make any needed revisions to the medications selected in the manner described above. Afterwards, the physician exits the medication manager 302 by clicking on the exit button 360.

Referring now to FIG. 23, a block diagram illustrates the structure of the optional legacy data system 106 as shown in FIG. 1. The legacy data system 106 includes a data source 370 and a converter 372. The data source 370 comprises physical data 374, such as paper based records and photographs, and electronic mainframe data 376. The converter 372 receives information from the data source 370 and transforms the information into an electronic format compatible with the EMR system. For example, to input physical data 374, such as paper or image based data, into a patient record, the converter 372 comprises a scanner to digitize the physical data into a binary file format for incorporation into the patient's record. To input electronic mainframe data 376, the converter 372 employs the same mechanism used for transfer or receipt of patient data from external sources. As described before, the converter 372 determines if an interface exists for the mainframe data, selects the appropriate data handler and converts the data into the proper format for incorporation into a patient record.

II. EMR System Configurations

FIG. 24 illustrates one possible configuration for the EMR system of the present invention. The system comprises a wide area network (WAN) 402, the World Wide Web (Web) 404 portion of the Internet, and remote web servers 406, 408, 410 communicating with web browsers 412. The WAN 402 comprises a plurality of local area network (LAN) servers supporting local and remotely located healthcare providers. For example, the WAN 402 includes LANs supporting Scripps Health 414 and Sharp Memorial 430 in San Diego and Cedars Sinai 432 and Loma Linda 434 in Los Angeles, Calif. In one presently preferred embodiment, the server comprises a multi-processor personal computer hav-

ing Intel Pentium processors, such as a Compaq Proliant 4500R 5/100 Model 2, communicating with a fault tolerant, error correcting storage device, such as a Hewlett Packard 20XT Optical Jukebox having 20 gigabytes of storage capacity. The LAN 400 includes a backup server 426 and several peripherals, such as a scanner 424 to input documents and a laser printer 422 to print out documents. In a preferred embodiment, the LAN backbone comprises an Ethernet twisted pair cable configured in a general star topology. Similarly, the scanner 424 comprises a Fujitsu M3093EX scanner using Kofax KIPP ImageControls software and the laser printer 422 comprises a Hewlett Packard LaserJet 4Plus. Healthcare providers may access the LAN 400 using a desktop computer 416, a laptop computer 418 or wireless pen computer 420. In a preferred embodiment, the desktop computer 416 comprises a Compaq Deskpro 5/75 Model 630, the laptop computer 418 comprises a IBM ThinkPad 760CD and the pen computer 420 comprises a Fujitsu Stylist 1000 configured with a Solectek AirLAN PCMCIA network adapter for wireless LAN access. The EMR system also provides for communication through the World Wide Web. For example, remote healthcare providers may access the WAN 402 on the Web using the domain name "www.westcost.com" 436. Thus, a healthcare provider located in Boston, Mass. may access a patient record resident on the Scripps Health server 414, located in San Diego, Calif., using a web browser 412, such as Microsoft Explorer or Netscape Navigator, communicating with a Web server in Boston, Mass. having the domain name "www.boston.com" 406.

In a preferred embodiment, servers 414, 426, desktop 416, or laptop 418 computers and peripherals, such as printers 422 or scanners 424, communicate with each other and with the Web using a network operating system, such as Microsoft Windows NT, Windows 95 or Windows for Workgroups. Similarly, pen computers 420 use the Microsoft Windows for Pen Computing operating system. In another preferred embodiment, the servers, computers and peripherals communicate using an operating system supporting Web browsers on computer networks, such as Unix, Novell Netware or Apple System 7.0. In yet another preferred embodiment, the EMR system includes servers, computers and peripherals networked using mixed network operating systems, such as Unix, Netware and Windows. For example, the LAN 400 may operate on a Windows NT network operating system, whereas the LAN 430 may operate on an Apple System 7.0 network, and the Web server "www.boston.com" 406 may operate on a Unix operating system. Thus, the EMR system supports communication among a variety of hardware components, such as printers 422, scanners 424 and pen computers 420, using a variety of network operating systems, such as Windows, Netware or Unix. In a preferred embodiment, healthcare providers, such as clinics and laboratories, may also communicate with the EMR system using modem links and standard v.34 modem devices, such as a US Robotics Sportster 28,800 modem.

The EMR system includes several databases of electronic information, such as the medication manager 302 and the data manager 202. In a preferred embodiment, the EMR system implements a relational database language that conforms to American National Standards Institute (ANSI) standard SQL-92, a 580 page specification for the SQL relational database language. A database language standard specifies the semantics of various components of database management systems (DBMS). In particular, it defines the structures and operations of a data model implemented by the DBMS, as well as other components that support data

definition, data access, security, programming language interface and data administration. The SQL-92 standard specifies data definition, data manipulation, and other associated facilities of a DBMS that supports the relational data model. SQL is old in the art and additional information on SQL-92 is available in ANSI specification X3.135-1992, hereby incorporated by reference.

Similarly, in another preferred embodiment, relational databases in the EMR system support the Open Database Connectivity (ODBC) model. ODBC is an application program interface (API) that allows client applications running under Microsoft Windows to access data from a variety of data sources, including relational and non-relational DBMS. These data sources may reside on a client machine or they may be located on a remote server communicating through a network common to the client machine. Under ODBC, data sources may vary in complexity from shrink-wrap databases, such as Microsoft Access, running under Windows on a client machine to more sophisticated, proprietary relational DBMS running on a Unix server or mainframe computer. For a client application to access data from a data source, a dynamic link library (DLL) driver must exist for each data source to be accessed. For additional information on ODBC is available from Inside ODBC, by Karl Geiger, hereby incorporated by reference.

II. SUMMARY

The electronic medical record system of the present invention advantageously overcomes several limitations of existing technologies and alternatives. Because it is more efficient and cost effective to move data, instead of physical records and healthcare providers, the present invention eliminates the need to create and maintain any physical data records. In contrast to other systems, the present invention creates and maintains all patient data electronically. Thus, there is no need to find, pull, move, update, file and replace physical charts. As a result, healthcare providers no longer require substantial shelving and storage space for physical files. The present invention likewise eliminates the mishandling, loss and destruction of patient data typically associated with maintenance of physical data records.

Using the present invention, healthcare providers enter patient data immediately at the point of care. Thus, the EMR system captures each piece of data at its source at the time of entry, including time and healthcare provider identification. The EMR system thus provides a complete audit trail for all patient data. The audit trail, in turn, permits inexpensive analysis of outcomes, utilization and compliance. For example, outcomes typically refer to the effectiveness of a treatment plan. Thus, the EMR system enables a healthcare provider to analyze patient recovery times and incurred costs to measure the efficacy of the treatment plan. Similarly, utilization typically refers to how well available resources are utilizing time. Thus, the EMR system provides the capability to analyze utilization of physicians, nurses, staff and equipment as well as time utilization for patients, such as wait times for referrals, lab results and physician examinations. Lastly, compliance typically refers to conformance with government and accreditation standards and regulations. The EMR system provides tools to enable healthcare providers to measure conformance to standards and regulations. To facilitate entry of patient data at the point of care, the invention provides touch screens for entry of lab orders, medications, diagnoses and procedures. The invention likewise provides instant access to a patient's electronic medical record by authorized healthcare providers from any geographical location. Thus, the EMR system enables autho-

rized healthcare providers to access and update patient files using wireless pen-based personal computers. In addition, authorized healthcare providers can access a record while other healthcare providers use the same record. By providing simultaneous access to patient data, the present invention enables real-time collaboration among multiple healthcare providers.

The availability of electronic data permits instant, sophisticated analysis of a patient's clinical data. Thus, the EMR system can create graphs of a patient's vital signs and lab results or the system can provide an analyze patient information to identify medication interactions and allergies. Using the present invention, a healthcare provider can likewise select, sort, and analyze patient data to identify relationships among the data considered. In addition, the EMR system provides flexibility in the creation and maintenance of patient data repositories. Thus, the present invention can support a large healthcare enterprise distributed across a large geography as well as a single physician office. Moreover, the present invention ensures patient confidentiality through the use of a tiered password system. The EMR system provides several levels of security for access to patient data. For example, a system administrator may have global password access to any patient data for system maintenance and debug purposes, whereas physicians may have access only to patient records within their specialty and nurses and staff may have access to only those patient records within their immediate care. In addition, a patient may request restricted access to their data by only certain personnel. Thus, in contrast to physical records, the EMR system provides superior protection of patient data.

In addition, the present invention is useful in legal, manufacturing and general administration environments. For example, the present invention is capable of organizing, maintaining and protecting legal files in an attorney's office. Thus, the EMR system can store and retrieve scanned images of paper documents, such as deeds and assignments, as well as other native file formats, such as word processing files. The EMR system organizes and retrieves this data in a manner akin to that of a patient's medical record. Upon entry of a client data into the EMR system, attorneys can annotate documents, transfer information to and from other systems, or create new data for automatic filing in the client or case file. Similarly, the EMR system is useful for management of procurement or regulatory data in a manufacturing context. Thus, the EMR system can organize and maintain material safety data sheets (MSDS) as well as other data pertinent to materials procurement, such as conformance to specification measurements and inspection data for received lots, in a manufacturing environment. Lastly, the EMR system is useful for general administrative files in any organization. For example, the present invention is applicable to employee files in human resources, customer files in sales and approved suppliers in procurement. The EMR system can organize and retrieve data within these files in the manner as patient data in a patient data record. As discussed above, upon entry of a data into the EMR system, users can annotate documents, transfer information to and from other systems, or create new data for automatic filing in the respective file.

Those skilled in the art may practice the principles of the present invention in other specific forms without departing from its spirit or essential characteristics. Accordingly, the disclosed embodiments of the invention are merely illustrative and do not serve to limit the scope of the invention set forth in the following claims.

What is claimed is:

1. A medical records system, comprising:

a point of care system to capture patient data at a point of care wherein the point of care system comprises:

patient data capture to enter information provided by a patient,

a clinical data capture, in data communication with the patient data capture to enter clinical data for the patient,

an encounter data capture, in data communication with the patient data capture, to enter diagnoses and procedures administered to the patient, and

progress notes, in data communication with the patient data capture, the clinical data capture and the encounter data capture, to enter information related to changes in the patient's condition, and

a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system.

2. The medical records system of claim 1, further comprising a medication data capture, in data communication with the patient data capture and the progress notes, to enter medication information for the patient.

3. The medical records system of claim 1, further comprising a practice guideline for reference to accepted medical practices, wherein the practice guideline communicates with the patient data capture, the clinical data capture, the progress notes and the encounter data capture.

4. The medical records system of claim 3, further comprising a medication data capture, in data communication with the patient data capture, the progress notes and the practice guideline, to enter medication information for the patient.

5. A medical records system, comprising:

a point of care system to capture patient data at a point of care; and

a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system, wherein the patient data repository comprises a server computer having access to patient data stored in a relational database that accepts SQL data queries.

6. A medical records system, comprising:

a point of care system to capture patient data at a point of care; and

a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system, wherein the patient data repository comprises a server computer having access to patient data stored in a relational database that is ODBC compatible.

7. A medical records system, comprising:

a point of care system to capture patient data at a point of care; and

a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system, wherein the patient data repository comprises: a patient locator having a patient identifier, a data manager, in communication with the patient locator, to organize patient data for storage and retrieval using the patient identifier, and a data interface, in communication with the data manager, to transmit patient data to external systems and to receive patient data from the external systems.

8. The medical records system of claim 7, wherein the patient data repository further comprises:

- a cache, in communication with the data manager, to temporarily store the patient data for retrieval; and
- a data archive, in communication with the cache, to permanently store the patient data.

9. The medical records system of claim 8, wherein the cache is located on a server computer.

10. The medical records system of claim 8, wherein the cache is distributed across a computer network.

11. The medical records system of claim 8, wherein the data archive comprises a jukebox having at least one storage device.

12. The medical records system of claim 11, wherein the at least one storage device is a recordable optical disk.

13. The medical records system of claim 11, wherein the at least one storage device is a magnetic disk drive.

14. The medical records system of claim 7, wherein the data interface comprises:

- a communication interface to send and receive patient data from external systems;
- an interface manager, in communication with the communication interface, to set the communication interface for either transmission or receipt of the patient data from the external systems; and
- a data handler, in communication with the interface manager and with the communication interface, to convert selected patient data into a selected data format.

15. A medical records system, comprising:

- a point of care system to capture patient data at a point of care;
- a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system; and
- a reference database in communication with the point of care system.

16. The medical records system of claim 15, wherein the reference database comprises:

- a diagnosis module having diagnosis codes indicative of a condition of a patient;
- a procedure module, in communication with the diagnosis module, having procedure codes indicative of a treatment to administer to the patient; and
- a medication manager, in communication with the diagnosis module and with the procedure module, having information on medication to administer to the patient.

17. A medical records system, comprising:

- a point of care system to capture patient data at a point of care;
- a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system; and
- a legacy data system in communication with the patient data repository.

18. The medical records system of claim 17, wherein the legacy data system comprises:

- a data source having patient data; and
- a converter, in communication with the data source, to convert the patient data into a selected format for transfer to the patient data repository.

19. The medical records system of claim 18, wherein the data source comprises physical data.

20. The medical records system of claim 18, wherein the data source 20 comprises a mainframe computer having electronically stored patient data.

21. The medical records system of claim 18, wherein the converter comprises a scanner.

22. A medical records system, comprising:

- a point of care system to capture patient data at a point of care wherein the point of care system provides for annotation of the patient data; and

- a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system.

23. The medical records system of claim 22, wherein the annotation acknowledges review of the patient data.

24. The medical records system of claim 22, wherein the annotation includes instructions for patient care.

25. The medical records system of claim 22, wherein the annotation indicates approval.

26. A medical records system, comprising:

- a point of care system to capture data at a point of care; and
- a patient data repository, in communication with the point of care system and with external systems, to store and organize the data in a patient record for access by the point of care system, wherein the data comprises interface files and wherein the patient record includes, a patient identifier, and at least one data structure including the patient identifier and the data.

27. A medical records system, comprising:

- a point of care system to capture data at a point of care; and
- a patient data repository, in communication with the point of care system and with external systems, to store and organize the data in a patient record for access by the point of care system, wherein the data comprises legacy files and wherein the patient record includes, a patient identifier, and at least one data structure including the patient identifier and the data.

28. A method of using an electronic medical records system, comprising the steps of:

- capturing patient data electronically at the point of care;
- organizing the patient data so as to form a patient record;
- filing the patient record; and
- retrieving the patient record to access the patient data for use in the care of a patient.

29. The method of claim 28, wherein the step of retrieving the patient record includes annotating the patient data.

30. The method of claim 28, further comprising the step of evaluating the patient data so as to make a diagnosis.

31. The method of claim 30, wherein the step of evaluating the patient data comprises consulting a diagnosis module to review diagnosis information.

32. The method of claim 30, further comprising the step of prescribing a medication.

33. The method of claim 32, wherein the step of prescribing a medication comprises consulting a medication manager to review medication information.

34. The method of claim 30, further comprising the step of administering a treatment.

35. The method of claim 34, wherein the step of administering a treatment comprises consulting a procedure module to review procedures to administer the treatment.

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36. A method of retrieving patient data in an electronic medical records system having a patient data repository, comprising the steps of:

obtaining a patient identifier;

locating a patient record corresponding to the patient identifier in the patient data repository;

determining the location of the patient data within the patient record.

37. The method of claim 36, further comprising the step of delivering the patient data.

38. The method of claim 36, wherein the patient data repository includes a cache and a data archive.

39. The method of claim 38, further comprising the step of delivering the patient data when the patient data is located in the cache.

40. The method of claim 38, further comprising the steps of:

moving the patient data from the data archive when the patient data is not located in the cache; and

delivering the patient data.

41. A method of managing a patient data repository having a cache and a data archive, comprising the steps of:

monitoring a status of data within the cache; and

moving the data to the data archive when the status exceeds a threshold.

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42. The method of claim 41, wherein the threshold comprises a selected time and the status comprises the duration of time the data has been in the cache.

43. The method of claim 41, wherein the threshold comprises a selected portion of the storage capacity of the cache and the status comprises the filled portion of the cache.

44. A method of communicating with an external source having an interface to an electronic medical records system, comprising the steps of:

finding an interface for the external source;

connecting to the external source using the interface; and

converting patient data for transfer between the external source and the electronic medical records system.

45. The method of claim 44, wherein the step of converting patient data for transfer comprises converting patient data for transfer from the electronic medical records system to the external source.

46. The method of claim 44, wherein the step of converting patient data for transfer comprises converting patient data for transfer from the external source to the electronic medical records system.

* * * * *

Full Name: Thomas Bergert

Job Name: Microsoft Word -

Location: Northern Virginia

Printer: NVA_7B

Submitted: 7-08-05 11:04:52 am

Printed: 7-08-05 11:06:12 am

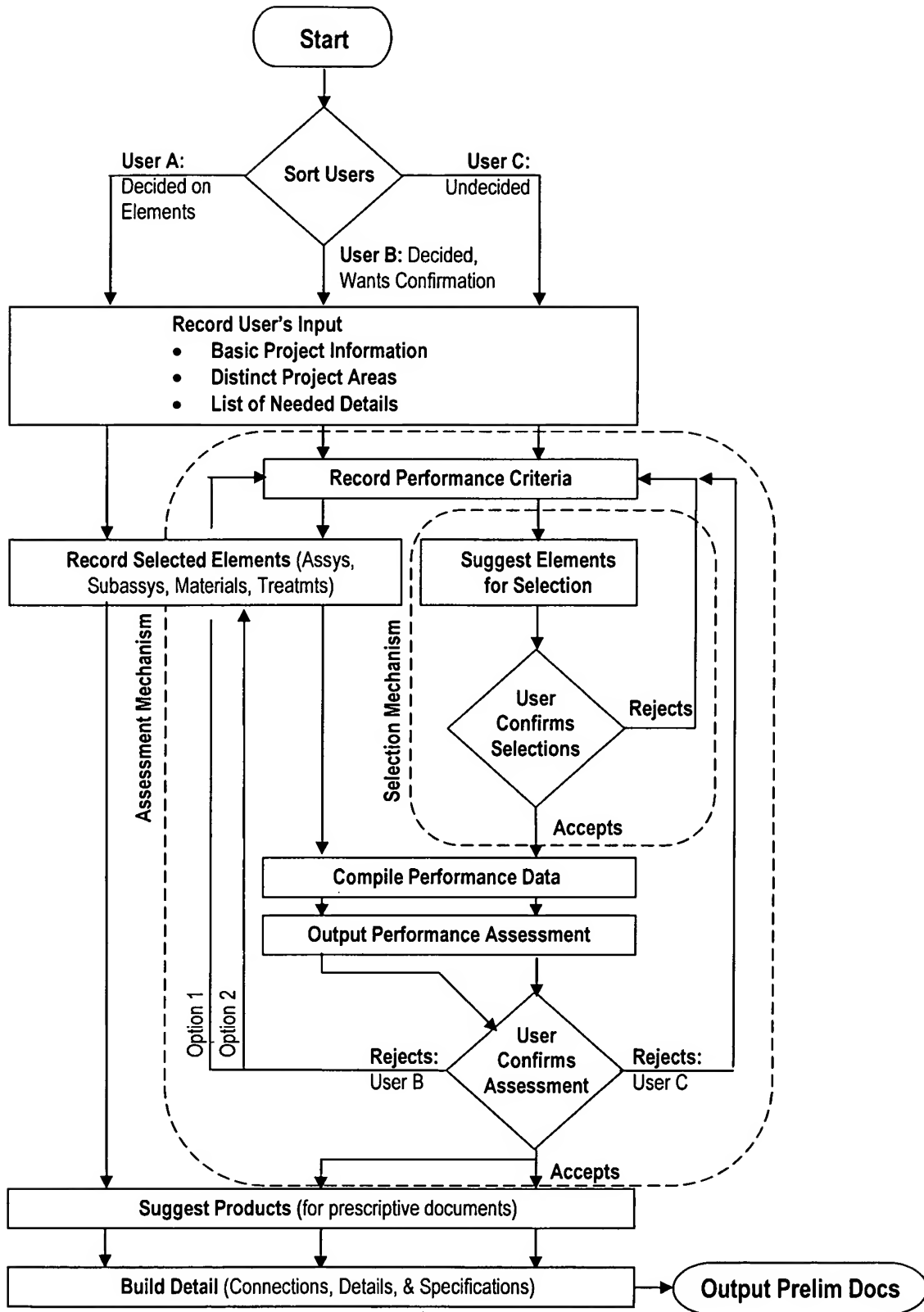


Fig 1: Element-Based User Process, with Mechanisms Identified

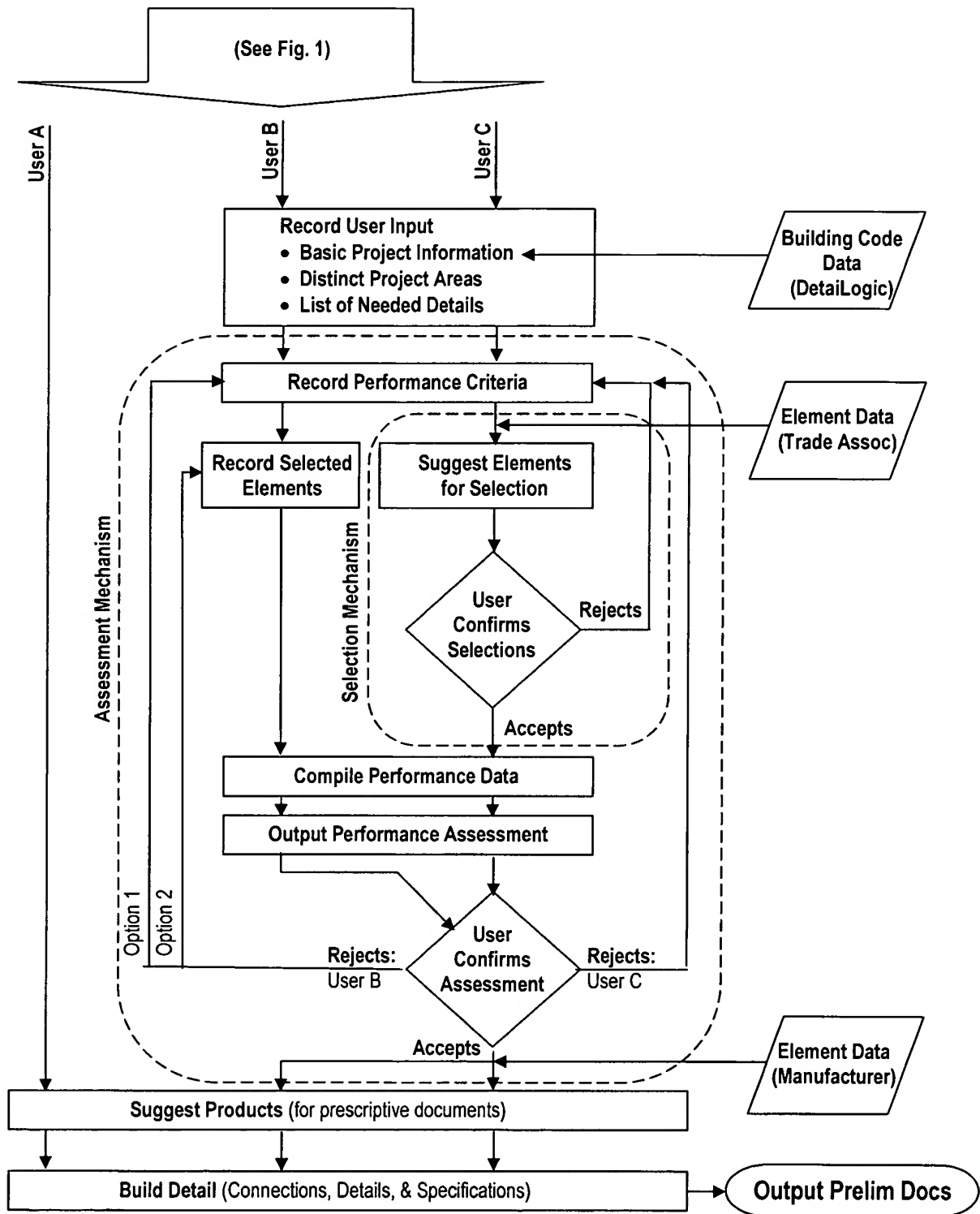


Fig 2: Opportunities for Data Input in Element-Based Process

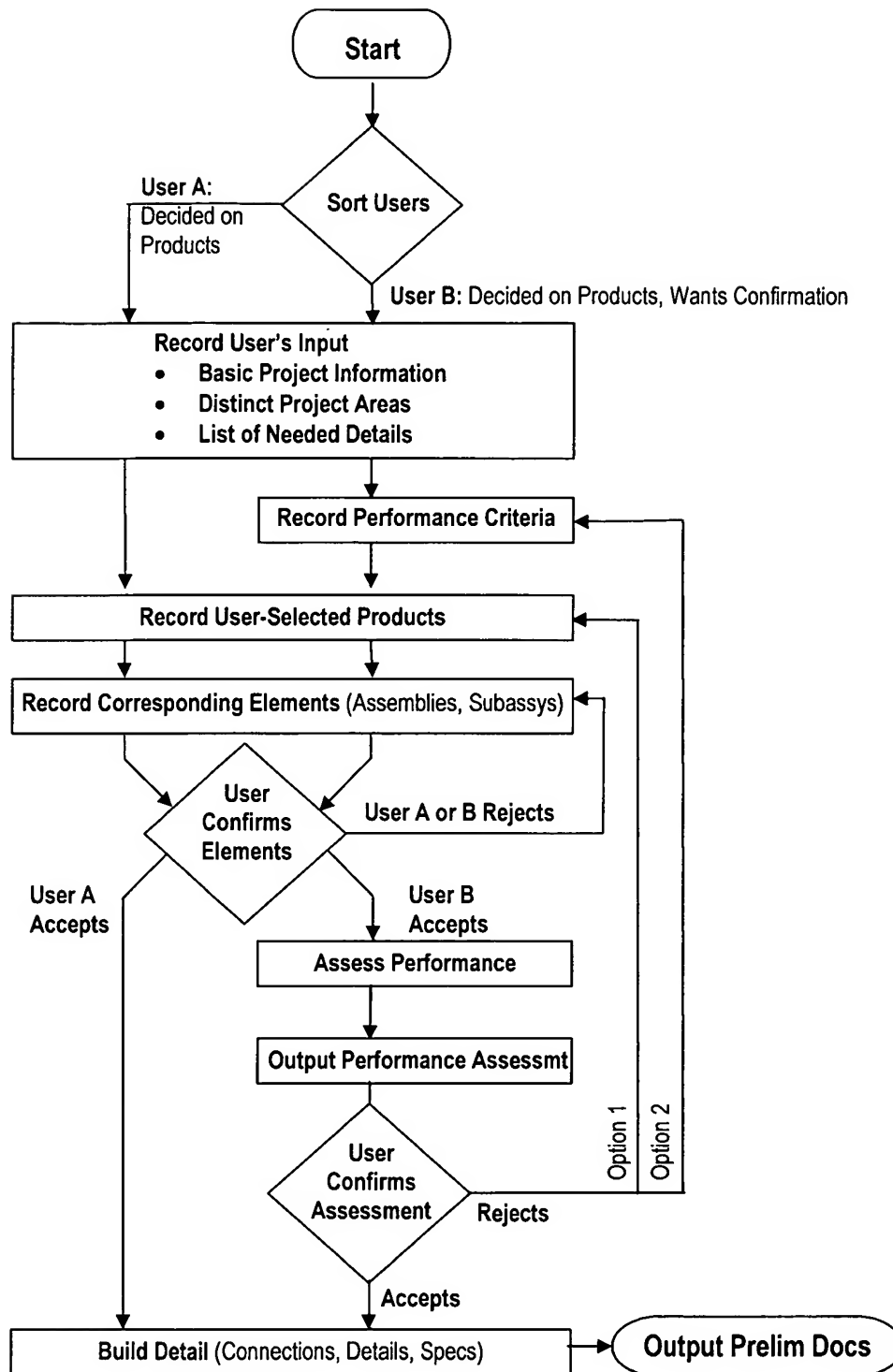


Fig 3: Product-Based User Process (Valid for User Types A and B only)

DetailLogic Basic Mechanisms

1. User inputs: All Users
 - a. Basic Data: Project Name, Zip Code, Jurisdiction, Status (new or renovation), Size, Fire Suppression, Street Frontage, and Program (occupancy type or use group)
 - b. Users' preferred path from 3 alternates
 - i. User Type A: Make all selections
 - ii. User Type B: Make selections but have DetailLogic confirm performance
 - iii. User Type C: Ask DetailLogic to make selections
 - c. Users' preferred focus from 2 alternates
 - i. Focus E: User picks elements
 - ii. Focus P: User picks products
 - d. Users' designation of Project Areas, subsets within the project that share a common set of elements (styles, forms, assemblies, subassemblies, materials, and treatments), and therefore a common set of details and specifications. Some projects may have only one such area, others may have a few or even many such areas. Users input a name for each area and provide a brief description of what makes it distinctive. The name is used in subsequent screens to identify the part of the project currently being processed.
 - e. Users' complete list of needed details (e.g.: parapets or eaves) based on the basic configuration of the design in each Project Area. Users simply pick detail types from an offered list.
2. DetailLogic Preliminary: All Users
 - a. From inputted Zip Code, Jurisdiction, and Status:
 - i. Look up applicable building codes
 - b. From inputted Size (area and height), Fire Suppression, and Street Frontage
 - i. Suggest possible Construction Classifications
 - ii. Ask Users to pick one.
 - c. From selected Construction Classification and inputted Occupancy Type
 - i. Look up applicable provisions in applicable Building Codes.
 - ii. Use them to narrow the range of qualified elements (assemblies, materials, etc.).
 - iii. Display only qualified elements in subsequent screens.
3. DetailLogic Intermediate
 - a. User A Focus E (Element)
 - i. Ask Users to choose element sets for each Area, including choices for Forms, Styles, Assemblies, Subassemblies, Materials, and Treatments. To continue with this sequence, Users must specify all elements at all levels. Those who don't will be directed to the User C approach and DetailLogic will suggest choices for the missing elements. Under that scenario, Users can choose any number of elements, in any order, and leave blanks for any for which they'd like suggestions from DetailLogic. All selections made are saved for use in ensuing steps.

DetailLogic

- ii. Search products database to find products whose performance fulfills the requested criteria. List them for Users, ranked in order of closeness of match. Users determine how many suggestions they want presented.
- iii. Ask User to identify products to be used from those suggested. If any are accepted, replace generic data with proprietary data. Where no product is selected for a particular element or group of elements, DetailLogic will proceed using generic information.
- b. User A Focus P (Product)
 - i. Ask User to choose product sets for each Area and for each Subassembly within each area. To continue with this sequence, Users must specify all products. Those who don't will be directed to the User C approach where they will identify performance criteria and let DetailLogic suggest choices for elements related to the missing products. Any products that have been selected are saved for use in ensuing steps.
 - ii. Ask Users to identify specific Assembly and Subassembly applications for each of the selected products. For example, a user might pick "Armstrong foil-faced R-19 fiberglass batts" and then identify it as applying to the thermal separation subassembly and to both enclosing wall and soffit assemblies.
 - iii. Show to Users, get confirmation
- c. User B Focus E
 - i. Present Users with a list of performance categories.
 - ii. Ask Users to identify performance criteria for each category that they feel is germane. Users can identify as many or as few criteria as they like. DetailLogic will ask Users to repeat the process for as many elements as the User cares to establish performance criteria. DetailLogic will ask for:
 - 1. The relative priority of each category of performance
 - 2. A qualitative range of performance required
 - 3. A quantitative range of performance required, including
 - a. A quantity
 - b. A unit of measure
 - c. A standard test for measuring performance, including
 - i. The test designation
 - ii. The publisher of the test
 - iii. The version of the test
 - iii. Where only qualitative criteria are identified, preventing DetailLogic from conducting an objective search of its database, DetailLogic can make the list available to manufacturers if so requested by Users.
 - iv. Ask Users to choose element sets for each Area, including choices for Forms, Styles, Assemblies, Subassemblies, Materials, and Treatments. To continue with this sequence, Users must specify all elements at all levels. Those who don't will be directed to the User C approach and DetailLogic will suggest choices for any missing elements. Under that scenario, Users can choose any number of elements, in any order, and leave blanks for any for which they'd like suggestions from DetailLogic. All selections made are saved for use in ensuing steps.

DetailLogic

- v. Compile performance data for each of the chosen element sets. For example, for all of the subassemblies in a given assembly, add the requested R-values, the requested dollar costs, the likely weight, the requested STC rating, etc. Where a User requests values for assemblies as a whole, DetailLogic will tabulate such values along with the totaled values on the constituent subassemblies to be able to report any discrepancies.
- vi. Show results of performance compilation to Users, ask for confirmation. If rejected, Users can either revise the performance criteria requested or select a different combination of elements. If accepted, continue.
- vii. Search products database to find products whose performance fulfills the requested criteria. List them for Users, ranked in order of closeness of match. Users determine how many suggestions they want presented.
- viii. Ask User to identify products to be used from those suggested. If any are accepted, replace generic data with proprietary data. Where no product is selected for a particular element or group of elements, DetailLogic will proceed using generic information.
- d. User B Focus P
 - i. Use a hybrid of the process outlined for User B Focus E and the process outlined for User A Focus P.
- e. User C Focus E (Focus P is not an option)
 - i. Use the process for User B Focus E, steps 3.c.i through 3.c.iii.
 - ii. Search the DetailLogic database of generic elements to find Forms, Styles, Assemblies, Subassemblies, Materials, and Treatments that meet the requested performance criteria.
 - iii. Show the found elements to Users, ranked within each group by degree of fulfillment of requested criteria
 - iv. Ask Users to choose elements from list presented. Where none of the found elements is acceptable, Users can go back to step 3.c.ii and modify the requested performance criteria.
 - v. Continue with the process for User B Focus E, steps 3.c.v through 3.c.viii.
- 4. DetailLogic Final: All Users
 - a. Build Detail
 - i. Compile subassemblies and products into assemblies
 - 1. Search the database for the CAD drawing files that correspond to the selected subassemblies or products. Conduct the search using imbedded attributes that match the performance criteria categories and listings. Format all drawings in the database in a standard way to make each drawing interchangeable with all other drawings showing subassemblies or products of the same type.
 - a. Draw each with a standard element thickness, ready to be stretched to the specific thickness needed.
 - b. Draw each for a standard set of conditions, so that each drawing is actually a series of drawings depicting
 - i. internal conditions such as inside corners, outside corners, angles and curves,

- ii. termination conditions such as copings, casings, fascias, eaves, sills, heads, and jambs,
 - iii. interruption conditions such as joints and penetrations, and
 - iv. transfer conditions such as rigid, pinned, and roller connections.
 - c. Draw each with an embedded set of insertion points at strategic locations. For example, draw support subassemblies with unique insertion points embedded at top and bottom inside and outside edges, the places where interior and exterior surface subassemblies would be attached.
 - d. Format drawings in compliance with the latest release of the National CAD Standard for layering conventions, line weights, symbols, etc.
2. Adjust each series of drawings so that the thickness between faces corresponds to the subassembly thickness selected. This would use a technique akin to the AutoCAD “stretch” command and, like all of the processes not identified as being taken by Users, would be accomplished with no direct action by Users.
 3. Gather the individual files for all of the subassemblies that constitute a single assembly. Align the individual thickness-adjusted subassembly drawings using their corresponding insertion points to create a series of assembly drawings for each of the specific conditions described above in 4.a.i.1.b.
 4. Save the compiled set of drawings as a new file representing the selected assembly.
- ii. Compile Assemblies into Connections
 1. Background: Each of the details previously identified by Users as being needed (in 1.e above) is composed of a series of connections. DetailLogic knows which connections are needed to make each of those details, enabling the next group of steps.
 2. Gather all of the individual files that contain drawings of the assembly conditions needed for one of the connections.
 3. Merge the assembly condition drawings into a single connection drawing using standard insertion points as noted above in 4.a.i.1.c.
 4. Show compiled connections to Users. If several options meet a similar number of performance criteria, show them all.
 5. Ask User to choose one. If all proposed connections are rejected, take Users back in the process to make different selections.
 - iii. Compile connections into details
 1. Background: Since DetailLogic deduced the needed connections from the requested details, going back from connections to details requires only reassembly.
 2. Gather all of the individual files that contain drawings of the connections needed for one of the details.
 3. Merge the connection drawings into a single detail drawing using standard insertion points as noted above in 4.a.i.1.c.
 4. Show compiled details to Users. At this point, only one detail will likely work.

DetailLogic

5. Ask User to accept the proposed detail. If it is rejected, take Users back in the process to make different selections.
- b. Compile element specifications into a comprehensive specification.
 - i. Search the database for the specifications files that correspond to the selected subassemblies or products. Conduct the search using imbedded attributes that match the performance criteria categories and listings. Format all text using CSI SectionFormat standards and conventions.
 - ii. Show to Users, get confirmation
- c. Repeat 4.a and 4.b for all details until the entire scope of drawings and specifications is created.
- d. Repeat entire process for other Areas.
- e. When drawings and specifications for all Areas are created, ask Users for their preferred format of output.
- f. Ask the User to take one of two actions:
 - i. Authorize DetailLogic to output the drawings and specs to the Users' computer. The User can then compile them manually into a single set of drawings and a single specifications book.
 - ii. Authorize DetailLogic to take over
 1. Arrange the drawings into sheets guided by the National CAD Standard and arranged by Areas where appropriate and produce a new compiled set.
 2. Collate the specifications into Sections and produce a new compiled set.
- g. Beyond DetailLogic, Users will further customize the documents and check them for quality before release.
5. Non-sequential processes
 - a. Progress: At any time, DetailLogic Users can check their progress by consulting a chart of assemblies on which DetailLogic will indicate that specific subassemblies or products have been selected. By clicking on each indicator, Users can display a thumbnail graphic of the associated subassembly or product. Progress can be gauged by noting the percentage of needed subassemblies or products that have been selected.
 - b. Help: DetailLogic contains hundreds of generic data sheets that provide information to guide Users in making selections between alternative elements including styles, forms, assemblies, subassemblies, materials, treatments, connections, and details. Context-sensitive help files can be accessed at any time by DetailLogic Users.

DetailLogic Extended Mechanisms

1. "What If" Analyses: Valid for User Types B and C only, since process requires identification of performance criteria.
 - a. Preliminary: Take Users through basic DetailLogic mechanisms outlined above, all the way through the end of Step 3, when all elements and products for a particular Area are tentatively selected.

DetaiLogic

- b. Intermediate: Allow Users to change any number of performance criteria, elements, and/or products, and then resubmit the new combination to the search process.
 - c. Final: When an acceptable new combination is proposed by DetaiLogic, one that complies with the revised list of performance criteria, elements, and/or products, send it through the Final process outlined above in Step 4. This can be done any time and as many times as needed.
2. Manufacturer and Trade Association Processes: Providing data for use by DetaiLogic Users
- a. Obtain data formatting guidelines form DetaiLogic for performance criteria, drawings, and specifications.
 - b. Prepare data in conformance with guidelines
 - c. Submit data to DetaiLogic for review
 - d. Obtain numeric tags from DetaiLogic that links data with DetaiLogic network.
 - e. Affix virtual numeric tags to data so it can be accessed by DetaiLogic subscribers as part of extended DetaiLogic database.

Full Name: Thomas Bergert

Job Name: outbind://10-000

Location: Northern Virginia

Printer: NVA_7B

Submitted: 7-08-05 11:05:07 am

Printed: 7-08-05 11:06:15 am

Bergert, Thomas

From: Barry D. Yatt [barry.yatt@verizon.net]

Sent: Thursday, July 07, 2005 10:24 PM

To: Thomas Bergert

Subject: Further patent documentation

Hi Tom,

Attached is my first stab at charts and a flow description. What else should I be doing? Send comments.

I hope to hear back from John tomorrow with a contract that we can execute. I leave Saturday morning and will not be back until Saturday night, July 23 except for all day on Tuesday, July 12 and the evening of Saturday, July 16.

Thanks,
Barry

7/8/2005



US006493724B1

(12) **United States Patent**
Cusack et al.

(10) Patent No.: **US 6,493,724 B1**
(45) Date of Patent: **Dec. 10, 2002**

(54) **WEB-INTEGRATED INVENTORY
MANAGEMENT SYSTEM AND METHOD**

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U.S.C. 154(b) by 283 days.

(21) Appl. No.: **09/597,484**

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(51) Int. Cl.⁷ **G06F 17/30; G06F 17/60**

(52) U.S. Cl. **707/104.1; 705/10**

(58) Field of Search **707/10, 104.1;
705/26, 10; 435/2**

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Assistant Examiner—Nguyen Camlinh

(74) *Attorney, Agent, or Firm*—Jacobson Holman PLLC

(57) **ABSTRACT**

An e-commerce exchange for gathering and managing a widely distributed inventory of blood, tissue and other samples for the biomedical research community and pharmaceutical industries worldwide. Samples belonging to registered sample providers are entered into a database at a central host site which is part of a distributed computer network. The samples are tagged by fields to cross reference the samples according to a number of specified criteria. Registered buyers search the database according to desired criteria. When the criteria of the search request matches the criteria specified for a particular sample, the central host site approves and supervises transfer of the particular sample from the supplier to the requesting buyer. Additionally, when the search request is not successful, there being no matching sample, the buyer may enter the requested sample criteria onto a wish list. A sample supplier having an unlisted sample meeting the criteria of an biological sample on the wish list may enter the sample into the database and the central host site will notify the buyer of sample availability and prompt transfer to the buyer.

19 Claims, 11 Drawing Sheets

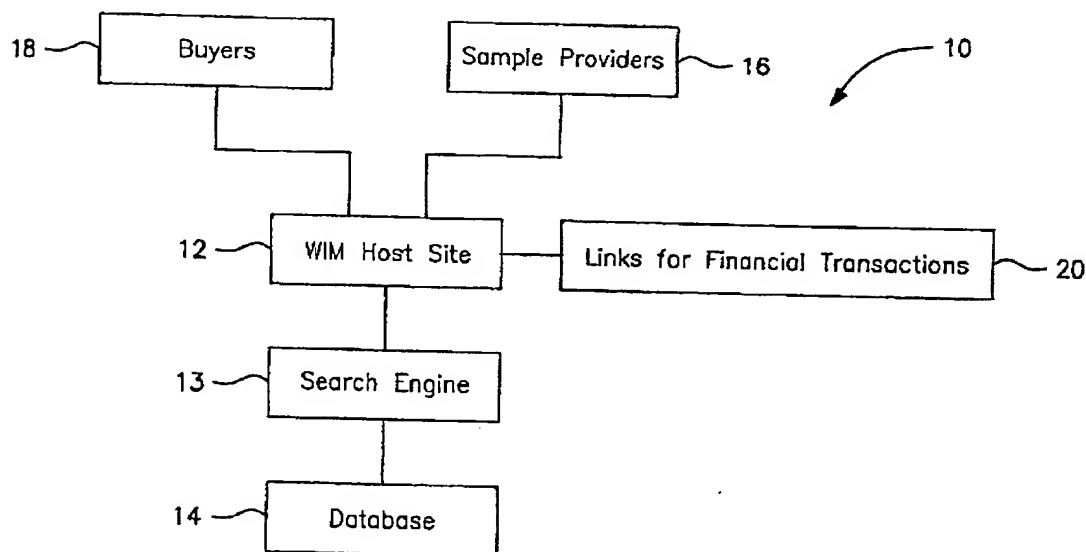
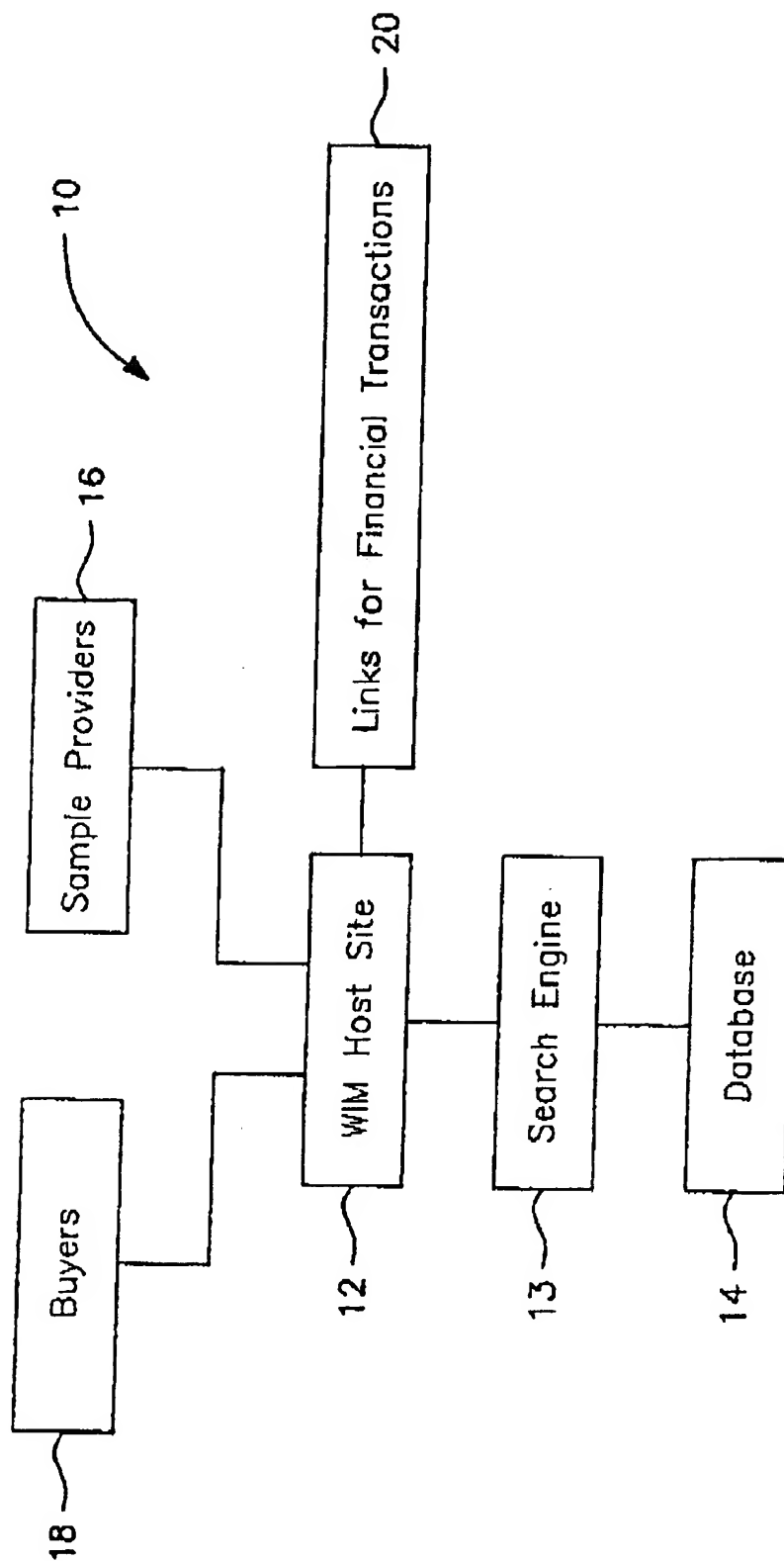


FIG. 1



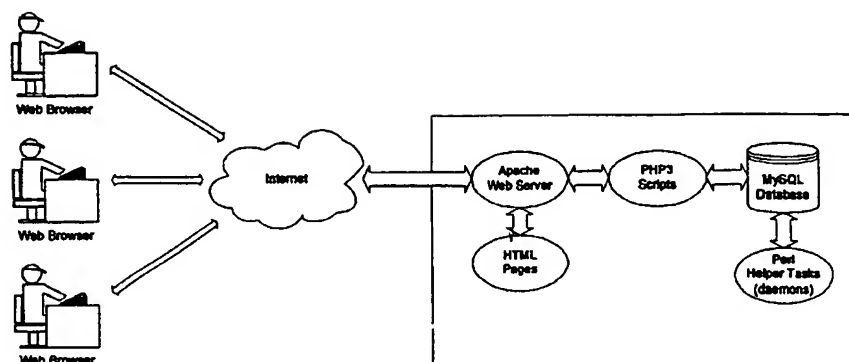


FIG. 2

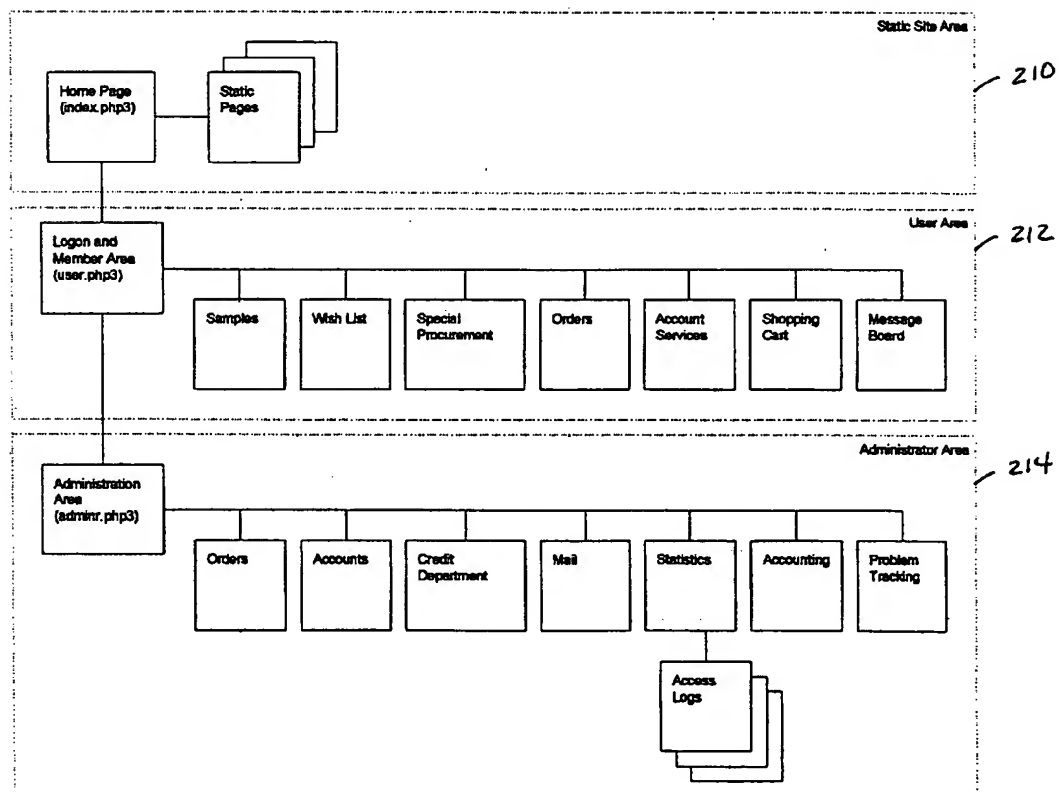


FIG. 3

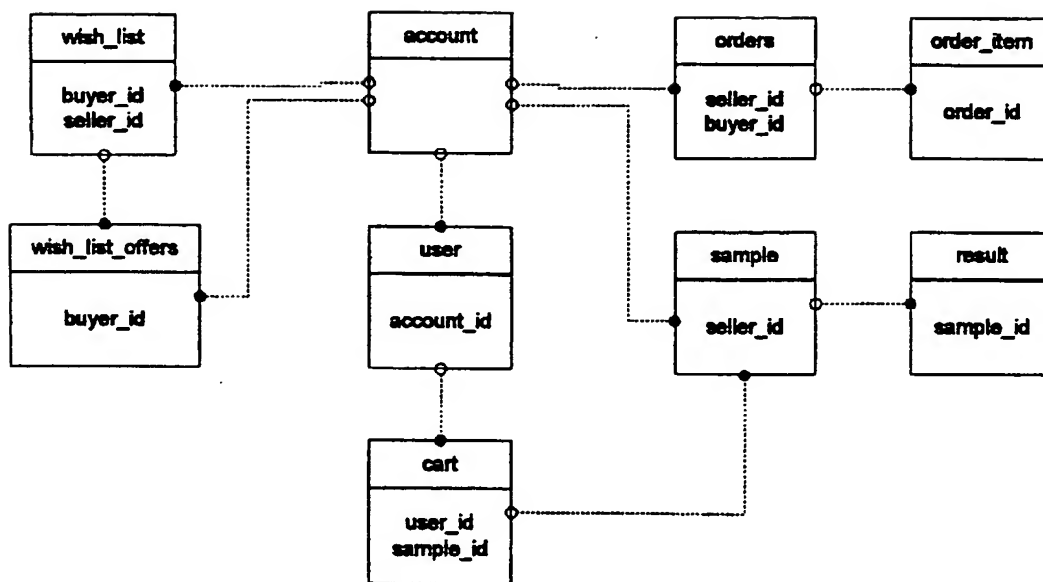


FIG. 4

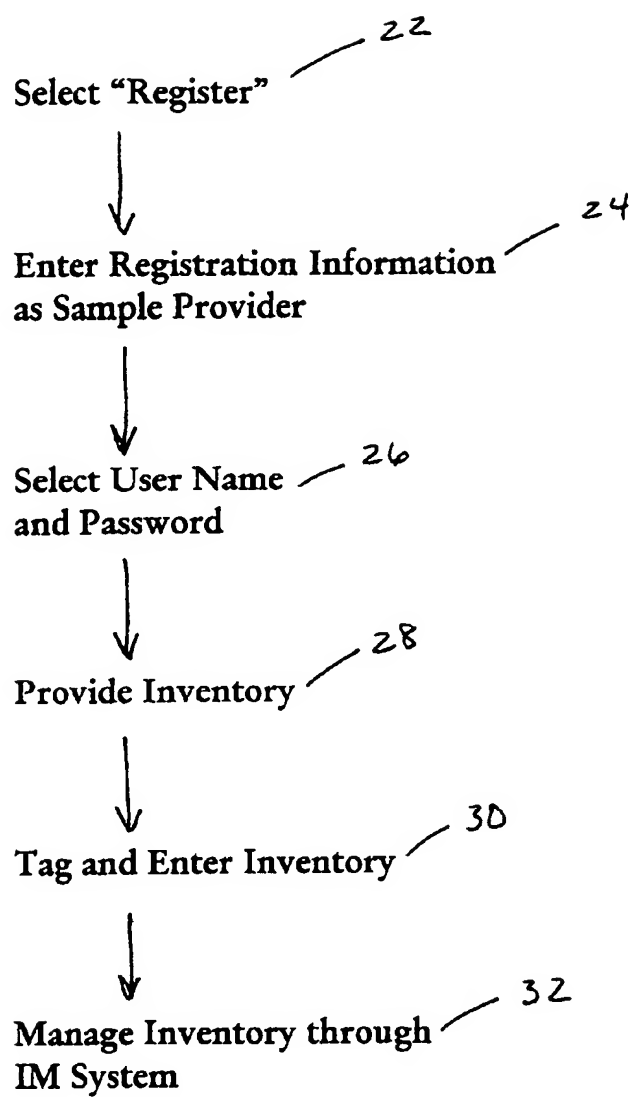


FIG. 5

LOG OFF

INVENTORY

SEARCH

GLOSSARY

PRODUCTS

HELP

The BIG PICTURE
Click here to read an overview of the system.

SAMPLES

WISH LIST

SHOPPING CART

ORDERS

ACCOUNT SERVICES

New Sample

Required Fields are designated by Bold face field titles.

Sample Information

Volume ☒ mL ☐ gr. ☐ Bulk Sample

Matrix Price in US\$

Lab Id per ☒ sample ☐ unit of measure

Product 1

Name ☒ Product ☐ Diagnosis ☐ Drug

Value (optional < or >) Tested

Test

Manufacturer

Product 2

Name ☒ Product ☐ Diagnosis ☐ Drug

Value (optional < or >) Tested

Test

Manufacturer

Patient Information

Age Race

Gender

Patient Id

Birth Date yyyy-mm-dd ☐ Medical Record Available

Field of Medicine ☐ Doctor Certified

Oncology Information

Site Stage

Grade Status

21

FIG. 6

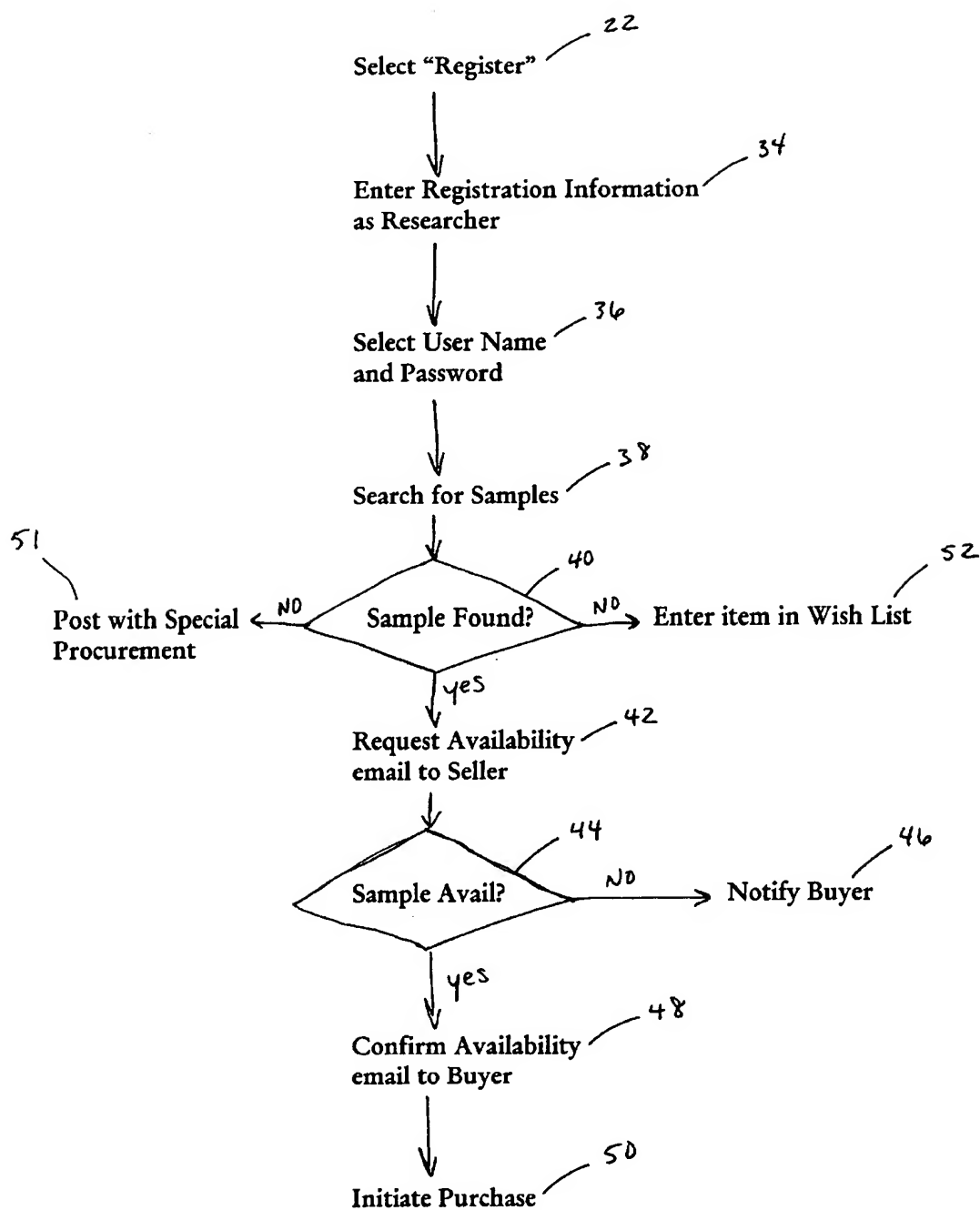


FIG. 7

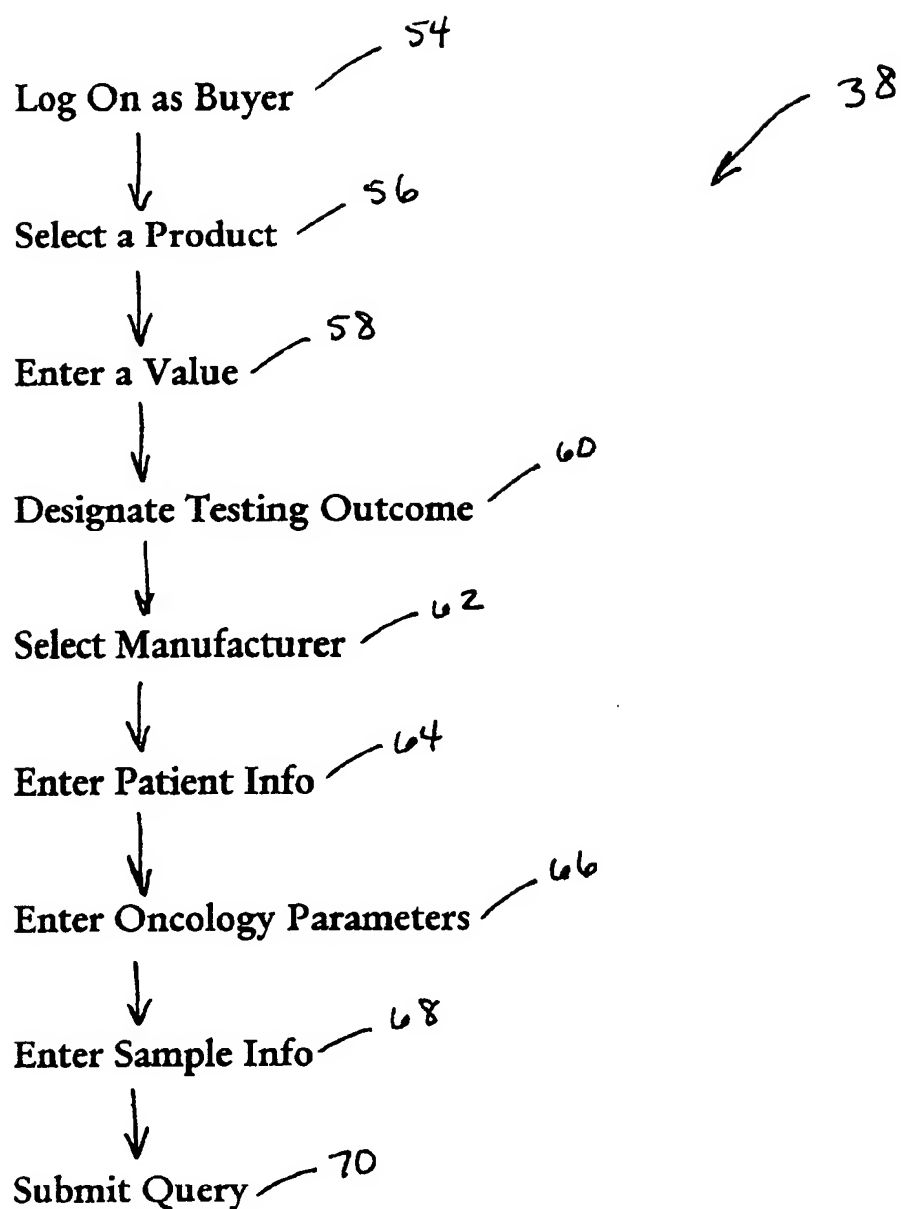


FIG. 8

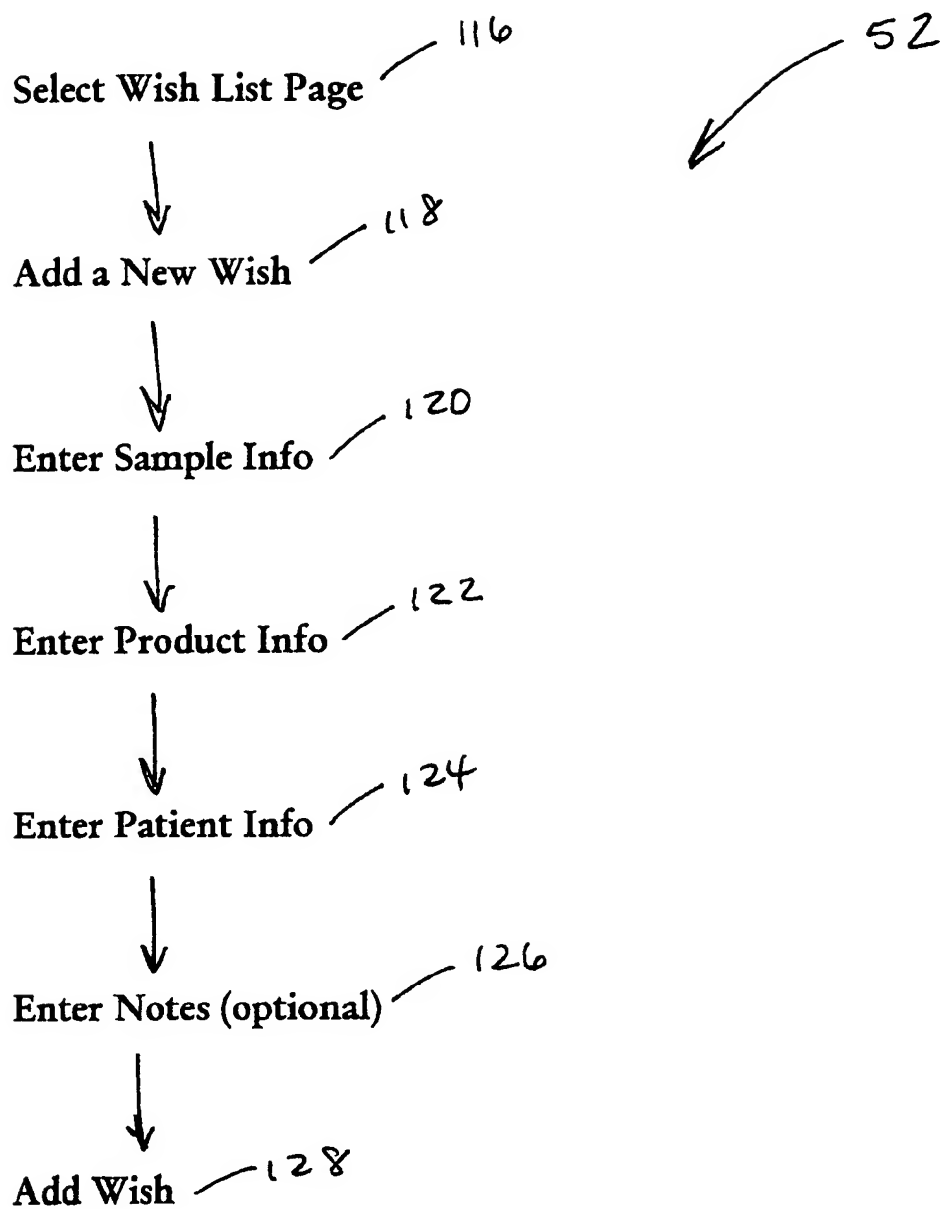


FIG. 9

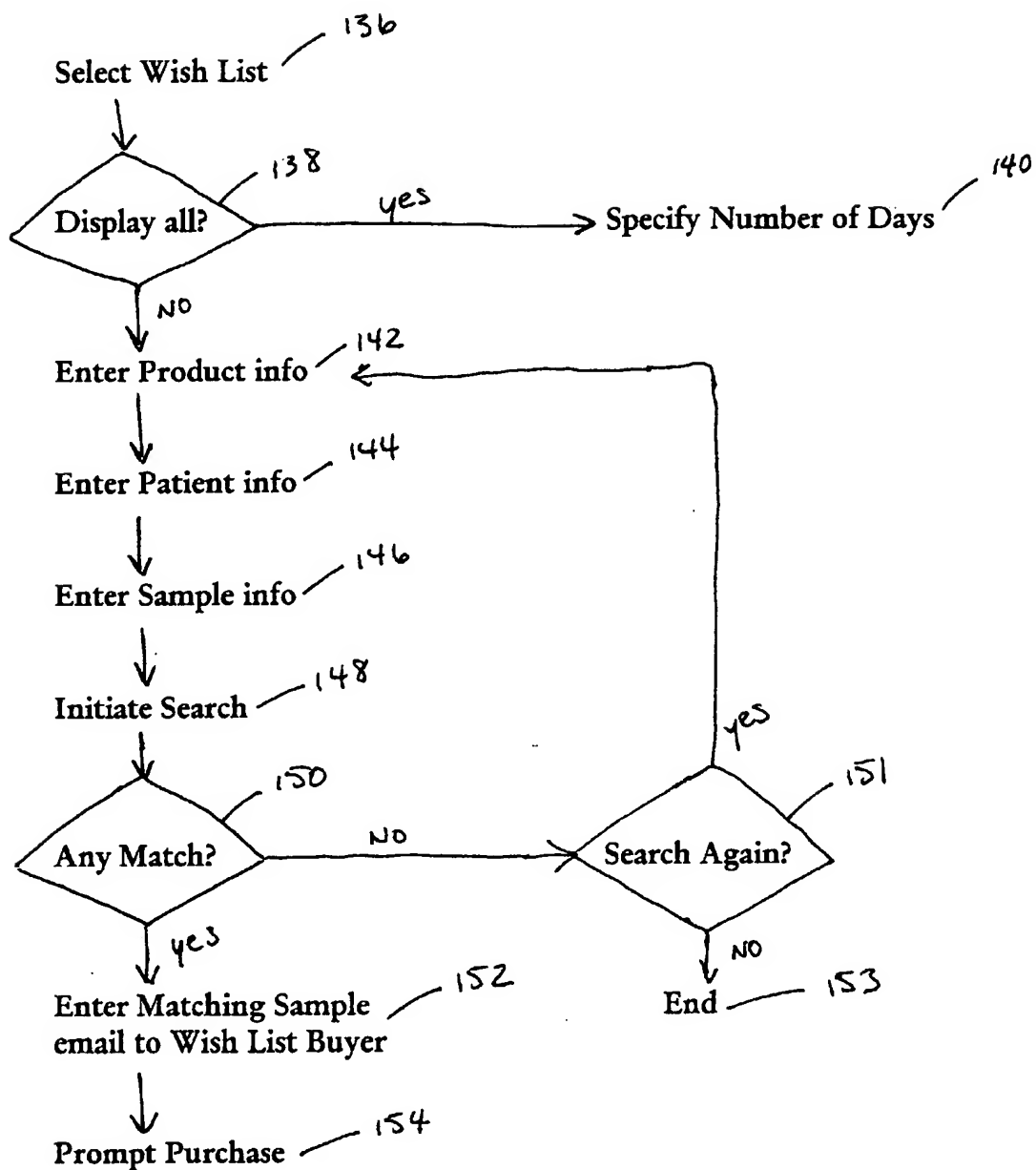


FIG. 10

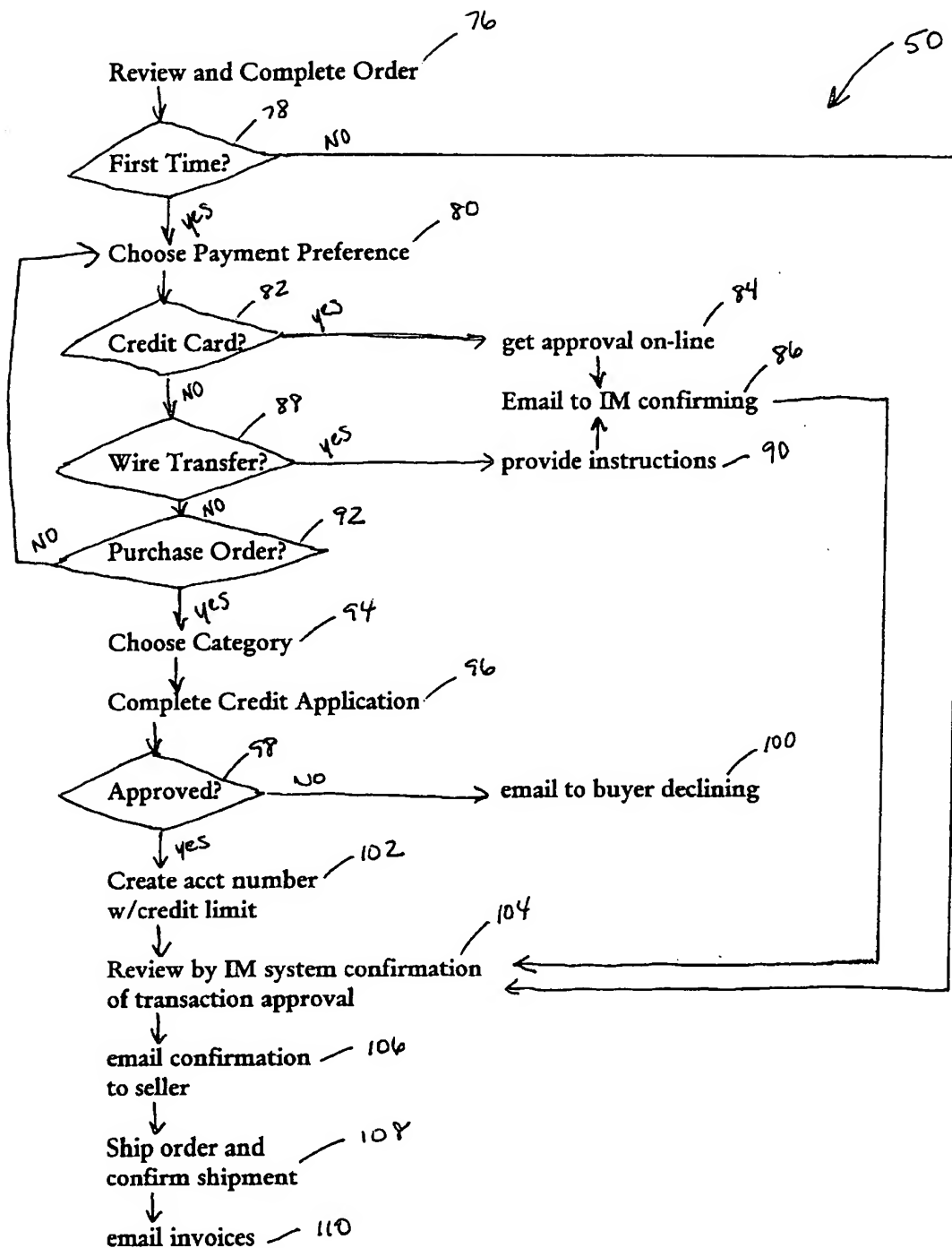


FIG. 11

SAMPLES WISH LIST SPECIAL PROCUREMENT ORDERS ACCOUNT SERVICES

LOG OFF Search Wish List Special Procurement

ADMIN PAGES

SEARCH

GLOSSARY


PRODUCTS

HELP

MESSAGE BOARD


THE BIG PICTURE


Quick Search (for Product, Diagnosis or Drug)


Quick Search 

Must be at least 3 characters

Product, Diagnosis or Drug

Search 

And (optional) 


Value Tested 

(Optional: <n, >n, or low-high)

Test


Manufacturer

Patient Information


Age 

(Optional: <n, >n, or low-high)

☐ Medical Record Available


Race 


☐ Doctor Certified


Gender 

Oncology Information

Site

Stage 


Grade 


Status 

Sample Information


Volume mL or gr.

(Optional: <n, >n, or low-high)


Matrix 

Provider 

☐ Bulk Sera

Sample Id 

☐ Multiple Matrix

Lab Id 


Field 

FIG. 12

WEB-INTEGRATED INVENTORY MANAGEMENT SYSTEM AND METHOD

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is related to the field of on-line computing and, more particularly, to a computer-based system and method for managing a dynamic and widely distributed inventory of biological samples or other perishable items and materials.

2. Description of the Related Art

To date, scientists and clinical researchers have spent valuable time and resources searching for the biological samples, such as blood, tissue, serum, plasma, bodily fluids, etc., that are essential to allow them to research, diagnose and help expedite cures for the world's vast number of diseases and other medical conditions.

Research sample needs are currently only partially fulfilled and are conducted by telephone, facsimile and time consuming networking between sample providers such as doctors, hospitals, laboratories, collection agencies and research product brokers. Using current methods, it often takes weeks to obtain even basic research samples; the procurement of rare samples can take months and even years, if they can be obtained at all.

Accordingly, there is an unmet need and increasing demand in the biomedical/pharmaceutical industry for accessible research products and related data.

SUMMARY OF THE INVENTION

In view of the foregoing, one object of the present invention is to overcome the difficulty in obtaining the biological samples necessary for research and other medical developments through a web-integrated inventory management system.

Another object of the invention is a sophisticated, yet simple to operate, one stop e-commerce exchange.

A further object of the invention is a search engine capable of searching for and locating samples according to a multitude of parameters which could not previously be designated on sample inventories.

A still further object of the invention is an inventory management system allowing sample providers to post their inventory in seconds and obtain worldwide exposure.

Yet another object of the invention is an on-line inventory management system that gives biomedical companies the ability to manage their inventories from designated and secure shelf space accessible to them through any web-enabled computer.

Another object of the invention is an integrated system for searching, finding, purchasing and receiving biological samples in a convenient, cost-effective and timely manner.

In accordance with this and other objects, the present invention is directed to a system and method for use with a distributed computer network, such as the Internet, that enables researchers, and others, to search for and purchase samples of biological material according to specified criteria. Through the present invention, sample buyers and sellers are brought together to a degree not previously available, increasing the value of the samples, both in terms of purchase price and research contribution.

The web-integrated inventory management (WIM) system of the present invention comprises a central host site

having a search engine for accessing at least one central host site database. Each sample provider wishing to subscribe to the WIM system provides the central host site with information describing an inventory of biological samples belonging to the sample provider. Each biological sample is tagged according to a plurality of fields. The fields identify the sample by specifying various criteria for or parameters of the sample. Tagging the samples by field essentially indexes the samples, cross-referencing them according to the specified parameters. The field information associated with each sample is then entered into the central host site database.

As the sample provider obtains additional samples, the sample provider can key in these later samples by hand, tagging the fields as desired. Alternatively, the sample provider can send the sample information to the central host site for tagging and entry of the sample into the central host site database.

By subscribing to the WIM system, sample providers may be relieved of the need to manage their own inventory and can instead choose to rely upon the monitoring and updating services provided by the WIM system. Each subscribing sample provider is afforded a designated password-protected "shelf space" with which they can do as they wish, providing them with what is essentially a worldwide storefront window and at very low cost to them. Because the inventory management system is web integrated, sample providers can access their inventories from any location having Internet access.

Researchers and other sample buyers search the WIM system database by specifying desired criteria by field. The WIM search engine searches the central web site database for matches to the request according to the information provided in the tagged fields. If a sample matching the request is not available, the buyer can place the request on a listing of desired but currently unavailable samples, i.e., a wish list. Responsive to a posting on the wish list, the WIM host site automatically generates email messages to subscribing sample providers, informing the sample providers of the desired criteria and that a prospective buyer has posted a request to purchase a sample meeting these criteria.

If a sample provider has, or subsequently obtains, a sample matching the criteria of a wish list item, the sample may be added to that provider's inventory as a new sample. The WIM host site automatically and routinely compares existing inventory sample data to items listed on the wish list. Upon detecting a match between the new sample and a specific wish list request item, the WIM host site generates an email notifying the buyer that a sample meeting his or her wish list criteria is available, and prompts purchase.

If a sample meeting all the specified criteria is available, the buying sequence may be initiated. This sequence is commenced by the buyer requesting availability of the sample. Responsive to this request, the WIM host site generates an email to the appropriate sample provider. The email includes a hyperlink to the host site. The sample provider confirms sample availability by clicking on the hyperlink and then checking which samples are available. The WIM host site then generates and sends an email to the buyer identifying the confirmed samples.

To purchase, the buyer selects a form of purchase, e.g., purchase order, wire, credit card, etc. Upon approval of the order by the central host site, a confirmation is sent to the buyer and to the sample provider, and the order is shipped.

These and other objects of the invention, as well as many of the intended advantages thereof, will become more

readily apparent when reference is made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of the web-integrated inventory management (WIM) system in accordance with the present invention;

FIG. 2 is a diagram of a site architecture in accordance with one embodiment of the present invention;

FIG. 3 is an illustrative overview of the contents of the WIM host site of FIG. 1;

FIG. 4 is a representative arrangement of tables within the database of FIG. 1;

FIG. 5 is a flowchart of the process of sample provider registration within the WIM system of FIG. 1;

FIG. 6 is an illustrative data entry screen for adding a new sample, in accordance with the present invention;

FIG. 7 is a flowchart summarizing buyer registration, sample search and sample purchase, in accordance with the present invention;

FIG. 8 is a more detailed flowchart of the sample search process of FIG. 7;

FIG. 9 is a more detailed flowchart of the entry of an item to the wish list process of FIG. 7;

FIG. 10 is a flowchart summarizing sample provider searching of the wish list, in accordance with the present invention.

FIG. 11 is more detailed flowchart of the purchasing process of FIG. 7; and

FIG. 12 is an illustrative data entry screen for the sample searching process of FIG. 8.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In describing a preferred embodiment of the invention illustrated in the drawings, specific terminology will be resorted to for the sake of clarity. However, the invention is not intended to be limited to the specific terms so selected, and it is to be understood that each specific term includes all technical equivalents which operate in a similar manner to accomplish a similar purpose.

As illustratively shown in FIG. 1, the present invention is directed to a web-integrated inventory management (WIM) system, generally designated by the reference numeral 10. The system includes a central WIM host site 12 having a search engine 13 for accessing a database 14. Sample providers 16 and buyers 18 access the WIM host site 12 through a distributed computer network such as the Internet. The WIM host site 12 also has links for the financial transaction 20 necessary to complete inventory transfer.

The WIM system 10 provides means for buyers 18 and sample providers 16 to match their needs and available products, respectively. Registered sample providers and buyers may each initiate searches of the database 14 of the WIM host site 12 using the search engine 13. The result is maximum utilization of the available samples, and the enhancement of research and other clinical efforts to cure medical conditions.

The WIM host site 12 is preferably embodied as a web site accessible over the Internet. As such a site, the host site may be configured in a number of ways, as would be known by persons of ordinary skill in the art; the following general overview of the site is for illustrative purposes only.

FIG. 2 is an illustrative example of the site architecture. As shown in this example, web browsers provide the user interface, PHP3 scripts provide business logic, and a MySQL database provides data storage. A set of helper tasks or daemons written in Perl may be run on a regular basis to regenerate indices, update database flags, backup databases, etc., as scheduled by a Unix host system. Such a Unix system may be provided in a virtual server environment.

FIG. 3 provides an illustrative overview of the host site and its contents. As shown, in preferred embodiment the host site includes a static site area 20, a user area 212, and an administrator area 214. The static area may be controlled using a main template script, e.g., index.php3. Although generated using a script, the area is referred to as static because it makes no use of the database.

A user.php3 script is the gateway to the dynamic part of the system. This script provides log-on services as well as the menu structure for the user area 212. Users belonging to the administrative group are able to enter the administrative area 214, which is representatively controlled through admin.php3 scripts.

Upon logging onto the WIM host site 12, the accessing user is greeted with a "Home" page which is within the static area 210. The "Home" page is the gateway to the site and provides the accessing user with an overview of the site's available information and procedures. Other pages or folders may be selected by clicking on the visible tabs and/or listed links as would be known by one of skill in the art. Pages may include, among others: "About Us", which summarizes information pertaining to the sponsoring host site; "Q & A", which presents frequently asked questions and the answers thereto; "Site Map", which summarizes the contents of the site with a listing of available page, that can be accessed by clicking thereon, and also provides a listing of support and purchasing information; "Contact Us", which provides address, phone and computer contact information of the host site sponsor, as well as promotional information; and "Register", which offers the accessing user the options of choosing to register as a sample provider, as a researcher, or as a guest. Each page, once accessed, contains multiple links to other pages, as is known to those of skill in the art.

The layout of the web pages can also accommodate advertising, particularly as pertaining to products and services relating to the biological and medical fields. Advertising may be incorporated throughout the pages or may be accessed through an advertising page or hyperlink, as desired. This option provides an excellent opportunity for product and service providers in the clinical research and related medical fields to target consumers having an interest in these specialized product and service areas.

All the data in the host site is stored in the database 14, which may be embodied as one or more MySQL databases. The database includes a plurality of tables; a representative arrangement of such tables for a preferred embodiment is provided in FIG. 4. Several other tables for various purposes are also maintained, and the tables are regenerated on a periodic basis.

In the embodiment shown in FIG. 4, all tables in the database have a unique identifier field, called "id". This field is used to link related tables. For example, the user table has a field called account_id that is related to the account table id field. The seller_id and the buyer_id fields refer to the account id of the sample provider and buyer, respectively.

As shown in FIG. 4, the host site centers on the account table. This table contains all the information pertaining to a particular account. An account can have one or more users,

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samples, orders and wish list entries. The main user file of the account table indicates the users to which official correspondence will be sent.

The user table contains the users of the system. A user has one shopping cart, and belongs to one account. The sample table contains information about the samples. A sample belongs to one account. The results table contains specific information about products, drugs, or diagnosis associated with a sample. A sample can contain zero or more results.

Each user has an independent shopping cart, which is stored in the cart table. Researchers are allowed to search the system and add samples to the cart. For each item in the shopping cart, the user id of the buyer, the id of the sample, and the desired amount is stored in the table. Once the buyer wishes to place an order, the system creates an entry to the orders table, and the samples in the shopping cart are transferred to the order_item table. From this point on, the order and associated samples are tracked from the order_item table.

The database 14 resident at the WIM host site 12 contains an extensive inventory of biological samples belonging to a plurality of sample providers 16. This information is maintained in the sample table. In order to list sample inventory through the host site, each sample provider 16 must first register with the WIM system. This registration process is set forth in FIG. 5.

A sample provider wishing to register first accesses the WIM host site 12 using a web-enabled computer. In this document, "web-enabled computer" refers to a computer having all the necessary hardware and software, e.g., modem, browser, etc., correctly installed as would be known by one of skill in the art so as to enable the computer to be linked to a distributed computer network such as the Internet for access to and exchange of electronic information.

As used herein, a "web-enabled computer" is also understood to be enabled for electronic messaging such as transmission and receipt of email communications. However, it would be possible to implement the present invention without the use of email, relying instead on facsimile transmission, for example; such alternative embodiments are also covered by the present invention. However, in the preferred embodiments, email communication is utilized.

Upon accessing the WIM host site 12, the sample provider 16 selects the "Register" page 22 as an option from the "Home" page. The register option may be resident on a page accessed from the "Home" page, may be a selection button on the "Home" page, or may be made accessible to the sample provider in any other manner as would be known by those of skill in the art.

Upon access to the "Register" page, the sample provider selects the option to register as a sample provider and enters pertinent registration information 24. Such information should include at least the name of the organization, address and phone, URL, and email address. The registration information also requires entry of one of a CLIA number, an FDA registration number or a medical license number. (The CLIA number refers to a state license issued to laboratories under the Clinical Lab Improvement Act.)

Following entry of the administrative information, the sample provider enters a user name and password 26. During subsequent contacts with the WIM host site, the sample provider uses the specified user name and password. If the sample provider forgets the password, the WIM host site will prompt entry of the email address as provided during registration. The system will then send an email to the registered organization identifying the correct user name and password.

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Once registered, the sample provider provides its inventory 28 to the WIM host site 12. Each sample is tagged and entered 30 into the database 14 of available samples. Samples are tagged by field to cross reference them in accordance with a variety of criteria. Sample fields may also be tagged for other purposes. Once the samples have been entered, sample providers may then manage their inventory through the WIM system 32.

The inventory management function of the present invention supports both sample providers wishing to list inventory for sale as well as companies with biological samples who desire inventory management capabilities but who do not have inventory they wish to sell. With particular focus on this latter group, in accordance with the WIM system of the present invention, such companies may license WIM system software. In a preferred embodiment, a copy of the WIM system software is loaded on one or more alternative secure web sites, separate from the WIM host site, and set up specifically for such inventory management support. Multiple inventories may, of course, be maintained at a single alternative site, with particular inventories accessed using a specific provider identification number or other code. Through such an alternative secure web site, licensed companies are able to access their inventory from any web-enabled computer, regardless of location. This capability also provides companies having a number of distributed offices, each of which may have a different internal computer system, with a centralized and unified means of tracking their company-wide in-house inventory that is simply not available in the prior art.

In an alternative embodiment, non-salable or maintenance inventory may be placed into the WIM host site database, but tagged to be non-viewable to prevent access by those parties searching the system to purchase samples. However, the preferred embodiment is to maintain sales inventory and maintenance inventory through separate WIM system sites. When used with specificity herein, "maintenance inventory" refers to biological inventory not offered for sale but being managed in accordance with the WIM system of the present invention. When not specifically identified as maintenance inventory, references to "inventory" are intended to include all kinds of inventory, whether being offered for sale or not.

As part of the inventory management function, whether through the WIM host site 12 or through an alternative web site supporting maintenance inventory management, the present invention further includes a bar coding capability for sample tracking. Through the WIM host site, or alternative site, electronic bar codes are provided to subscribing sample providers for each of their samples. These bar codes can include a range of information, as would be known by persons of skill in the art. The samples providers can download and print these bar codes using their own computer equipment and affix the resulting bar code labels on respective samples. Bar coding the samples enables automated sample retrieval and also enables the data identifying a particular sample to be transferred easily and electronically, whether within the sample provider's system or to an ultimate buyer of the sample. A buyer receiving a bar coded sample can use the information in the bar code to download the full record associated with the sample from the WIM host site, obviating the need to manually reenter the data into the buyer's computer. In that sample providers and purchasers may be dealing in hundreds of samples, this automation has tremendous value both in terms of time savings and the assurance of accuracy in sample information tracking.

Sample provider inventory information may be received in any number of formats dependent upon the sample

provider's particular computer system, including as examples, spreadsheet, word processing, database, CVS comma delimited files, etc. Furthermore, a single sample provider may have multiple offices and, in many cases such as when the sample provider represents a merger of companies, each of these offices may use a different computer system. Without the present invention, such sample providers are virtually unable to search for samples within their own multi-office inventories, there being no commonality across their systems and no solution short of installing an entirely new system to unify all of their offices.

In accordance with the present invention, input data as received from sample providers are translated into a standardized, web-searchable format. In a preferred embodiment, input data is exported to a CVS file, which is then parsed by a customized Perl script which imports the data into the WIM host site database. This represents a significant benefit, not only to parties wishing to search the inventory for purchase, for also to the sample provider who needs to know the availability of in-house samples.

To describe a sample, the WIM host site database preferably uses two tables, a sample table and a results table. The sample table contains a basic set of information that describes a sample and associated patient demographics. At a minimum, all samples contain one entry on the sample table.

The results table contains an arbitrary number of attributes that can be attached to a record in the sample table and which describe additional information about the sample beyond that placed on the sample table. In a preferred embodiment these attributes identify the search fields, but there does not have to be a direct correspondence between attributes and search fields. In general terms, the results table includes a label and a value. The label identifies an attribute or product, and the value represents a numerical value associated with the label. For example, the label may be "ferritin" with a value of 1.30. The search function performs searches over most of the fields of the sample table and over the label field on the results table.

According to the customization of the Perl script, customer record information is mapped to the host site database data record information. For each field provided in the customer data, the Perl script typically is configured to execute one of three options. The first option is for the script to map the customer sample field to one of the sample table fields. The second option is to append the customer sample field to the results table and associate that field with the sample table record for that sample. The third option is to ignore the field.

As part of the preparation of the customized import script, all fields that specifically identify the patient are tagged to be ignored. Fields so tagged are not copied into the WIM host site database. By stripping out personalized data, inadvertent disclosure is prevented, patient confidentiality is protected, and laboratories are encouraged to list more of their samples with the assurance that sensitive fields will not be listed with the sample.

In a preferred embodiment, only the laboratory identification (id) number or code given by the sample provider, and necessary for proper identification of the sample, is transcribed into the host site database. Furthermore, distribution of the laboratory id may be limited to the owner of the sample and to administrative host site personnel.

With large inventories, entry of samples is most efficiently transacted by downloading a computer file of the sample provider's database of inventory to the WIM host site.

Inventory provided to the WIM host site through a downloaded computer file is processed by the WIM host site. This processing converts the data received from the often proprietary systems of sample providers into the centralized system of the present invention using the customized Perl script just described, or equivalent import technique as would be known by those of skill in the art.

Smaller inventories or individual samples to be entered may be added on-line by the sample provider through the WIM host site using the "Sample Inventory Management" page, as is described in greater detail hereinafter. In a preferred embodiment, the "Sample Inventory Management" page allows the sample provider to add a new sample, edit an existing sample, or list all samples.

To add a new sample, the "Add New Sample" option is selected from the "Sample Inventory Management" page to bring up the "New Sample" page, shown representatively in FIG. 6. As with all pages described herein, the "New Sample" page is exemplary only and is not intended to limit the on-screen presentation to the particular format shown.

In a preferred embodiment, the "New Sample" page includes links to other pages or folders which may be selected by clicking on the visible tabs or linking text, as would be known by one of skill in the art. These pages may include, among others: "Wish List", which allows the user to add a new wish, search the listed wishes, etc.; "Shopping Cart", which facilitates collection of samples for purchase; "Orders", which summarizes ordering information and procedures; and "Account Services", which provides a listing of account activity and status.

As may be seen from FIG. 6, when new samples are entered into the database 14, each sample is identified according to a plurality of criteria, by fields, which describe or correlate with the sample. For example, instead of simply adding a sample to the database identified only as "blood", it is much more useful to researchers and others to know that the blood is of a particular type, came from a person of a particular race, demonstrates a particular abnormality, etc. Therefore, to maximize the utility of each sample, a plurality of criteria are specified for each sample, as appropriate to the sample type.

Representative categories of criteria to be identified for new samples as shown in FIG. 6 include sample information 15, patient information 17 and oncology information 19.

Sample information 15 may include volume, matrix, laboratory identification number and price. Whether or not the sample is a bulk sample may also be checked. Different or additional sample information may, of course, be used in accordance with the present invention.

Sample information may also include the designation of particular "products", with the embodiment shown in FIG. 6 illustrating two product designations, although additional product designations may also be included. For each "product", a product name, value, test outcome and method of test or test manufacturer may be entered. The "product" name may actually be directed to one of three subcategories, namely a product, a diagnosis or a drug, as shown. Additional details on sample information are included later herein.

Patient information 17 may include age, gender, race, patient ID, patient birth date, field of medicine, medical record available and doctor certified. Other or additional categories may also be included as appropriate. Additional details on patient information are included later herein.

Oncology information 19 may include site, stage, grade and status. Other or additional categories may also be

included as appropriate. Further details on oncology information are included later herein.

Upon completion of data entry into the required, as well as any desired, fields, the sample is added to the inventory by clicking on the "Add" button 21.

To edit an existing sample, the sample provider can identify the desired, sample by a sample identification number, "sample ID"; a laboratory identification number, "lab ID"; or a patient identification number, "patient ID". The sample provider designates one of these categories, enters the appropriate number into the designated data entry field, and clicks on the "Search" button. The desired sample is then accessed by the search engine 13 from the database 14 for editing.

To list all samples, the sample provider can click on the "List all Samples" option. A list of samples belonging to the sample provider is displayed. A representative sample list is provided in Table I.

TABLE I

ID	Lab ID	Matrix	Volume	Price
87888	12	Plasma	0.10 ml	12.00 per sample
87276	21215	Serum	12.00 ml	2.00 per ml
87294	32589	Plasma	0.20 ml	12.00 per sample
87279	96854	Serum	0.40 ml	4.50 per ml
87282	9696	Heparin	0.10 ml	8.00 per ml

As already discussed, the sample provider may manage inventory with the WIM host site, or alternative site, which is not available for purchase, if desired. However many, if not most, of the samples within the sample provider's inventory are typically available to buyers 18 for purchase.

Buyers include researchers and others having need of specified biological samples. For the purposes of this document, reference to "researchers" may be considered synonymous with reference to "buyers" and shall be used to indicate any party interested purchasing a sample through the WIM system 10.

Buyers 18 register with the WIM host site 12 in order to be able to purchase the samples. The buyer registration process, along with a general overview of the search and sample procurement process in accordance with the present invention is set forth in FIG. 7.

A buyer wishing to register first accesses the WIM host site 12 using a web-enabled computer. In response to the "Home" page, the buyer selects the "Register" page 22. The register option may be resident on a page accessed from the "Home" page, may be a selection button on the "Home" page, or may be made accessible to the buyer in any other manner as would be known by those of skill in the art.

Upon access to the "Register" page, the buyer selects the option to register as a researcher and enters pertinent registration information 34. Such information should include at least the name of the buying organization, address and phone, URL, and email address.

Following entry of the administrative information, the buyer enters a user name and password 36. During subsequent contacts with the WIM host site, the buyer uses the specified user name and password. If the buyer forgets the password, the WIM host site 12 will prompt entry of the email address as provided during registration. The host site will then send an email to the registered buyer organization identifying the correct user name and password.

Once registered, the buyer may search for samples 38. A sample search may be conducted as a quick search or as a detailed search.

The quick search is a feature of the present invention that enables the buyer to type in what he or she is looking for specifically, without having to enter the range of individual search criteria required for a detailed search. To use the quick search feature, the buyer must enter a minimum of three characters representing a word, or part of a word, with which to search a product, diagnosis or drug field. For example, a buyer wishing to find a sample with various types of measles as the product would enter "mea". All relevant results would then be located and shown, regardless of whether they were input originally as a product, drug or diagnosis.

To conduct a detailed search, the buyer enters specified criteria describing particular parameters associated with the desired sample. Because each sample is cross referenced in accordance with a plurality of attributes, the buyer is able to designate with great specificity, if desired, the particular nature and attributes of the sample desired. This is a capability simply not available in the prior art where searching is often limited to designating a matrix or a matrix and one other parameter. Using the present invention, by contrast, samples may be identified in accordance with multiple parameters, with one present embodiment including 18 or more. The buyer can also limit the search to samples from a particular provider. Of course, values for all parameters need not be identified when entering or searching for a sample. But there are times when having the option of searching in accordance with a significant number of parameters enables highly specific research needs to be very particularly and efficiently met. A more detailed description of the detailed search process 38 is provided in FIG. 8.

If the search does not locate an appropriate sample 40, a negative search result is returned and the buyer may either post the desired item with special procurement 51 or enter the specified criteria for the desired sample to the wish list 52. Again, the potential for designating multiple parameters greatly increases the value of these options.

Special procurement is a feature of the present invention that allows the buyer to post his or her needs in written form without the aid or constraint of designated fields. The buyer is provided with a general data entry field and is directed to enter in detail the type and amount of samples desired. When data entry is complete, the buyer clicks on a "post request" button, or other analogous submission means, to post the request with the WIM host site. Once posted, the WIM host site is notified, and a procurement specialist team is assigned from the host site to facilitate in obtaining the posted samples.

Alternatively, the buyer may enter the item into the Wish List 52. As already mentioned, the wish list is a listing of desired, but currently unavailable, samples. The wish list may be described as a "wanted" section for use by both researchers and sample providers. Researchers use the list to post requests for samples that are not presently available in the inventory. Researchers can also review their own wish lists and make modifications as needed. A more detailed description of entry of items to the wish list is provided in FIG. 9. The wish list may also be searched by sample providers, as set forth in greater detail in FIG. 10.

If the search does locate an appropriate sample 40, the buyer may request availability of the sample 42. Responsive to a request for availability, the WIM host site generates and sends an email to the appropriate sample provider. If the request for availability requests availability of samples originating with more than one sample provider, the WIM host site splits the request according to sample provider and sends an email to each provider.

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Each email identifies the sample or samples of interest and provides a hyperlink to the WIM host site. Each receiving sample provider clicks on the hyperlink and checks which sample or samples are available using a radio button or other equivalent means. To complete confirmation, the sample provider clicks on a "Confirm", or equivalent, button to send the confirmation to the host site.

Confirmation of sample availability is a valuable aspect of the present invention due to the fact that sample providers may sell their inventory through channels other than the WIM host site. When a sale is completed through the WIM host site, the database is automatically updated, concurrently or within a short time of the sale, removing from the listed inventory those samples which are no longer available. But since listing inventory with the WIM host site does not preclude the sample provider from transacting directly with other parties for sale of the samples, an item sold by the sample provider over the counter, for example, will not result in an automatic inventory update. Confirming availability enables the buyer to ensure that an advertised sample is indeed still in the sample provider's inventory.

If the desired sample is not available 44, the WIM host site notifies the buyer 46. If the sample is available 44, the WIM host site automatically generates and sends an email to the buyer confirming sample availability 48. A separate email is generated for each sample provider so that if three sample providers were polled for available samples, the buyer will receive three emails. The buyer may then initiate purchase 50 or cancel each order. A more detailed description of the purchase process is provided in FIG. 11.

Turning now to the search process as summarized in FIG. 8, the buyer begins by logging onto 54 the WIM host site using a web-enabled computer. Following log-on, he or she is presented with a data entry page for searching samples and may initiate a search. A representative sample "Search" page is provided in FIG. 12.

As shown in FIG. 12, the "Search" page includes a quick search feature as well as a plurality of data entry fields, many of which correspond to the data entry fields shown on the "New Sample" page of FIG. 6. Data within these fields define the specified search criteria for a detailed search and are compared by the search engine to data entered in corresponding fields in sample inventory, so that detailed searching is conducted on a field by field basis. As previously discussed, the quick search feature allows the buyer to search according to a minimum of three characters entered into the quick search data entry field.

In the preferred embodiment and using the detailed search option, entry of data into certain data entry fields is required while others may be left blank. Every field containing data is compared with the corresponding field of a sample in inventory. To achieve a positive search result, i.e., a match between the search request and a sample in inventory, all entered data fields in the search request must correlate with corresponding data fields in a single sample in inventory. Data fields that are left blank in the search request do not limit the search, i.e., so long as the entered data matches corresponding data field data in a single sample in inventory, the fact that the single sample in inventory may have data entered in data fields corresponding to the blank fields does not prevent a positive search result.

The present invention may also be embodied such that required data fields must contain corresponding data between the search request and the inventory sample, while data fields that are not required will not prevent posting of a "possible" match. The posting of a "possible" match

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allows the buyer to review the inventory sample to determine if the parameters listed represent a sufficient match to enable the sample to be of use to the buyer. This posting of "possible" matches is an alternative embodiment. In the preferred embodiment, all entered data fields must match a sample in inventory in order for a positive search result to be obtained. If any of the entered data fields does not match a corresponding field in the compared sample in inventory, a negative search result is obtained.

The buyer begins by selecting a "product" 56. More specifically, the "product" may be one of three subcategories including a product, a diagnosis or a drug. With reference to the subcategory, product refers to a disease or a condition in a defined matrix. Other or additional subcategories may also be included as appropriate in accordance with the function and purpose of the present invention.

The buyer selects one of product, diagnosis or drug by clicking on the appropriate subcategory. If the buyer is not familiar with the search engine, he or she may click on the search button at this stage, and may thereafter narrow the search.

In a preferred embodiment shown in FIG. 12, two fields are provided for entry of a product, diagnosis or drug. Having two such fields allows the buyer to search for a product under two subcategories, e.g., under both product and drug, both product and diagnosis, or both diagnosis and drug.

Upon selection of a "product", an A-Z listing of the selected subcategory is displayed and a specific item within that listing may be selected. Clicking on the first letter of the desired item results in display of a list of items beginning with that letter. To select one of the items, the buyers clicks on the item, which is then automatically entered into the "product" name field.

"Product information", which in this document is intended to include and also refer to information pertaining to products, diagnoses or drugs, as applicable, further includes values, testing results and test manufacturer. Values represent a quantitative number for the product, diagnosis or drug, and may be entered 58 as absolute values, such as 5, 10, 150, etc., or they may be entered 58 as ranges of numbers, such as from 10 to 100. Testing results may be designated 60 as either a positive or a negative finding. Test result may also specify the qualitative or quantitative analysis by a specific manufacturer. Finally, test manufacturer may be selected 62 to obtain results based on a specific type of testing machine or to specify the diagnostic supplier of a specific assay. By clicking on test manufacturer, an A-Z listing of manufacturers is displayed. The manufacturer selected is automatically entered into the test manufacturer field.

The buyer then enters patient information 64. In the preferred embodiment, patient information includes age, gender, race, medical record available and doctor certified. Other or additional categories may also be included as appropriate in accordance with the present invention.

Age may be designated numerically as a specified number, as less than a specified number, as greater than a specified number, or as within a specified range. Age may also be entered more generally as "low" or "high". Gender and race have pull-down menus with available selections listed.

Medical record available allows the buyer to limit the search to results which have medical records available. Doctor certified allows the sample provider to limit the search to results which have been certified by a physician.

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The buyer then enters oncology parameters 66. These may include site, stage, grade and status. The WIM search procedure may also be configured to include other or additional parameters as appropriate.

Finally, the buyer enters sample information 68. In a preferred embodiment, sample information includes volume, matrix, provider ID, sample ID, and medical field. Different or additional sample information categories may, of course, be used in accordance with the purpose and function of the present invention.

Volume is preferably designated as a specified amount and is given in units of either grams or milliliters. Optionally, the buyer may specify volume as less than a specified amount, more than a specified amount, within a particular range, or as "low" or "high".

Matrix may include, among others, bulk sera, bulk plasma, sera, plasma, cord blood, hair, saliva, semen, spinal fluid, stool, tissue, urine, whole blood, anticoagulants, and multiple matrix.

Provider ID typically designates the name of the provider. Sample ID refers to an identification number or code assigned to the sample during placement of the sample into the inventory of the database 14.

Medical field includes a listing of available medical field choices. A representative listing could include auto antibodies, cardiology, endocrinology, general chemistry, gynecology, hematology, infectious diseases, oncology, pathology, tropical diseases, dermatology, gastroenterology, musculoskeletal, urology, neurology, pediatrics, ophthalmology, pharmacology, pulmonary and rheumatology, and geriatric medicine. The medical field listing is displayed by clicking on the down arrow adjacent the medical field data entry field.

Once entry has been made to all required fields, the buyer submits the search query 70. In the preferred embodiment, such submission is accomplished by clicking on the "Search" button on the "Samples" data entry page. The steps then proceed as already discussed in connection with FIG. 7 and are dependent upon whether or not a sample is found 40. As already mentioned, if a sample is not found 40 and a negative search result is returned, the buyer may post the desired item with special procurement 51 or may enter the desired item into the wish list 52.

Sample providers review wish list requests to see if any such requests match items in their inventory which are unlisted in the database or which are designated as private inventory. Upon finding a match, the sample provider may enter the matching, but previously unlisted, sample into the database 14. The match is detected during a next routine review by the WIM host site for matches between inventory and the wish list entries. Upon finding the match, the WIM host site generates an email to the requesting researcher notifying the researcher that a sample meeting their listed criteria is now available.

Alternatively, when a buyer places an item on the wish list, the WIM host site generates an email to subscribing sample providers identifying the wish information. One or more sample providers may respond with an offer to the buyer of a specified sample, which is conveyed through the host site. Should the buyer accept the offer, the WIM host site notifies the sample provider of the acceptance. The sample provider then adds the sample to its inventory, and the WIM host site generates an email to the buyer listing the added samples. The buyer adds the samples to the shopping cart and the purchase sequence is initiated, as discussed in greater detail in connection with FIG. 11.

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The steps to be taken when adding an item to the wish list 52 are depicted in FIG. 9. The process begins by selecting the "Wish List" page 116 and then selecting the "Add a New Wish" page 118. The "Add a New Wish" page is a data entry page into which the buyer enters sample information 120, product information 122 and patient information 124. The buyer may also enter notes 126 as needed or appropriate.

In a preferred embodiment, sample information includes number of samples, price range, matrix and expiration date. Volume may also be included. Different or additional categories of sample information may, of course, be used in accordance with the present invention.

Number of samples may be designated numerically as a specified number, as less than a specified number, or as greater than a specified number. Number of samples may also be entered more generally as "low" or "high".

Price range may be designated numerically as a specified number, or as less than a specified number, and should include a price base, e.g., per sample, per unit, etc. Price range may also be entered more generally as "low" or "high".

Matrix specifies the form or substance of a sample. Matrix categories include whole blood, serum, urine, etc., and can also specify whether the sample is contained in bulk sera or is part of a multiple matrix. A multiple matrix may be comprised of multiple samples from the same patient, such as a whole blood sample and a urine sample. Generally, a multiple matrix is a collection of samples that belong to the same account, have the same lab identification number and different matrix. Samples may also be grouped into a collection known as a series. A series is a collection of samples that belong to the same account, have the same patient identification number and the same matrix.

Expiration date is typically entered by year, followed by month and day.

Volume may be designated numerically as a specified amount, as less than a specified amount, as greater than a specified amount, or as within a specified range. Volume may also be entered more generally as "low" or "high", and may be in units of milliliters or grams. Preferably the use of grams is limited to tissue samples.

In the preferred embodiment, "product" information may be designated according to three subcategories, namely product, diagnosis and drug, as has already been described. Other or additional categories may also be included as appropriate in accordance with the present invention.

The buyer selects one of product, diagnosis or drug by clicking on the appropriate subcategory. An A-Z listing of items within that subcategory is then displayed and a specific item may be selected. Clicking on the first letter of the desired item results in display of a list of items beginning with that letter. To select one of the items, the buyer clicks on the item name which is then automatically entered into the "product" name field.

In the preferred embodiment, patient information includes age, gender and race. Other or additional categories relating to patient information may also be included as appropriate in accordance with the present invention.

Age may be designated numerically as a specified number, as less than a specified number, as greater than a specified number, or as within a specified range. Age may also be entered more generally as "low" or "high". Gender and race have pull-down menus with available selections listed.

Once all required items have been entered, the buyer submits the new wish 128 to the wish list. In the preferred

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embodiment, such submission is accomplished by clicking on the "Add" button appearing on the "Add a New Wish" page.

The buyer may choose to review his or her wish list by selecting "My Wishes" from the "Wish List" page. The wishes are listed individually and specify, for each wish, an identification number, the date the wish was entered, the specified matrix, product name, and whether or not there is a match in the database. A representative wish list is provided in Table II. The researcher may review a particular wish in more detail by clicking on the appropriate identification number. The researcher may also delete a particular wish as appropriate, such as when a sample meeting the wish has been obtained.

TABLE II

ID	Date	Matrix	Product	Match
286	14 Jan 00	Serum	HSV	No
285	14 Jan 00	Serum	EBV	No
284	12 Jan 00	Whole Blood	Specific Proteins Assayed at 3 Different Levels	No
277	10 Jan 00	Whole Blood	Lyophilized Drugs Of Abuse Unassayed At Different Levels	No
274	10 Jan 00	Serum	Rubella	No

The researcher may choose to search the Wish List. In a preferred embodiment, the researcher can search the Wish List for all wishes that have been posted for a specified number of days. For example, the researcher can specify a search of all wishes posted to the list within the last ten days. Alternatively, the researcher may search for wishes that have been on the Wish List for at least a specified number of days.

In addition to the buyer's access to the wish list, sample providers may wish to search the Wish List. Referring now to FIG. 10, the sample provider may search the wish list by first clicking on the "Wish List" file tab to display the "Wish List Search" page 136. By entering data into the "Wish List Search" page, the sample provider may search for and display all wishes 138 posted within a specified number of days prior to the search. The default is 30 days, but alternative periods may be selected by specifying a number of days 140. Alternatively, the sample provider may use the "Wish List Search" page to enter product information 142, patient information 144 and sample information 146, and initiate a search.

In the preferred embodiment, "product" information may be designated according to three subcategories, namely product, diagnosis and drug, as has already been discussed. Other or additional categories may also be included as appropriate in accordance with the present invention.

The sample provider selects one of product, diagnosis or drug by clicking on the appropriate subcategory. An A-Z listing of items is then displayed and a specific item may be selected. Clicking on the first letter of the desired item results in display of a list of items beginning with that letter. To select one of the listed items, the sample provider clicks on the item name which is then automatically entered into the "product" name field.

Product information further includes values, testing results and test manufacturer. Values represent a quantitative number for the product, diagnosis or drug, and may be entered as absolute values, such as 5, 10, 150, etc., or they may be entered as ranges of numbers, such as from 10 to 100. Testing results may be selected as either a positive or

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a negative finding. Finally, results based on a specific type of testing machine may be obtained by clicking on test manufacturer to display an A-Z listing of manufacturers. The manufacturer selected is automatically entered into the field.

In the preferred embodiment, patient information includes age, gender, race, medical record available and doctor certified. Other or additional categories may also be included as appropriate in accordance with the present invention. Entry into these fields has already been described herein, and may be referred to as also applicable here.

In a preferred embodiment, sample information includes volume, matrix and notes. Different or additional sample information categories may, of course, be used in accordance with the present invention.

Volume is preferably designated as a specified amount. The database is searched for samples on the wish list entered in both milliliters and grams.

Clicking on "Matrix" reveals matrix categories that have been posted on the wish list. If the matrix being sought is not listed, then a sample with that matrix has not been posted on the wish list. If the matrix being sought is listed, then the appropriate selection is highlighted.

The sample provider may also search for a sample on the wish list based on the notes entered by the potential buyer posting the wish list item. For example, to search for a sample on the wish list with notes that include the word "sera", the word "sera" is typed into the notes field. Similarly, if searching for "bulk sera" those words are typed into the notes field. The search will identify samples using the exact combination of words appearing in the notes field.

Once all required field items have been entered, the sample provider submits the search query to initiate search 148. In the preferred embodiment, such submission is accomplished by clicking on the "Search" button near the bottom of the "Wish List Search" page.

If no match is found 150, the sample provider may choose to search again 151 using different criteria. If no additional searches are desired, the search ends 153.

If a match to the search query is found 150, the sample provider may choose to enter the matching sample 152 into the database 14. Once entered, the match will be detected by the WIM host site during a next routine review of inventory versus wish list entries. The WIM host site runs such reviews on a regular basis and preferably at least every 24 hours. Upon detecting the match, the WIM host site automatically generates an email message to the buyer who posted the matching wish list entry. The email message notifies the buyer that a sample meeting his or her wish list specifications is available and prompts purchase 154.

The steps to be undertaken when initiating a purchase 50 are set forth in FIG. 11. Once a sample has been identified and found to be available, the buyer reviews and completes an order 76 for the sample. Orders are stored in the database in the orders and order₁₃ item tables. The ordering process may include selecting the desired samples and placing them into a temporary holding status, such as an electronic shopping cart, from which items may be deselected if desired.

As noted earlier, the present invention may be configured to include advertising, most typically relating to the clinical research and medical fields. Display of some advertisements may be sensitive to the particular items being purchased, in a manner somewhat akin to the printing on grocery store receipts of coupons for the future purchase of particular

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items responsive to the buyer's currently purchased items. Therefore, in response to the purchase of a particular matrix, for example, products supporting or otherwise relating to that matrix may be presented to the buyer for inclusion in the shopping cart. The buyer is, of course, free to ignore the prompts and can proceed with purchase of the desired samples.

If the purchase represents the first time 78 the buyer has purchased, the buyer must choose a payment preference 80 and be approved for purchase.

If the buyer chooses to pay with a credit card 82, approval is typically obtained on-line 84 from an outside entity through the links for financial transactions 20. The outside entity sends an email 86 to the WIM host site confirming that approval has been granted or denied. Other means of obtaining approval may also be employed.

If the buyer chooses to pay with a wire transfer 88, the buyer provides transfer instructions 90 on a wire transfer instruction page, including bank coordinates for the wire transfer. The wire transfer instruction page also includes a date box to be filled in with the date when the wire was sent, the bank name and the country name. An email to the WIM host site confirms 86 the transfer.

If the buyer chooses to pay with a purchase order 92, the buyer chooses a category 94. In the preferred embodiment, the categories include Fortune 1000, universities and others, although other categories may also be specified in accordance with the present invention. The appropriate credit application is provided to the buyer responsive to the category selected; in the preferred embodiment, Fortune 1000 companies receive immediate credit approval upon registration.

Credit applications may be sent electronically or via facsimile, mailing, etc. The buyer completes the credit application 96, as applicable, and sends it to the WIM host site. At the WIM host site, received credit applications are placed in a credit application folder. In the preferred embodiment, this is a password protected folder maintained by the host site. Received credit applications are reviewed by personnel at the WIM host site. If the application is not approved 98, the WIM host site generates an email to the buyer declining 100 the buyer's request to purchase by purchase order.

If the credit application is approved 98, the WIM host site generates an account number with a specified credit limit 102 appropriate to the particular buyer. Account numbers and associated credit limits are placed in a credit accounts folder maintained at the WIM host site. The account number and credit limit of the approved buyer are then provided to a purchase authorization folder maintained at the WIM host site.

In the preferred embodiment, the purchase authorization folder is a password protected folder. All emails confirming transaction approval, whether from credit card 82, wire transfer 88, or purchase order 92, are directed to the purchase authorization folder. Transaction approval is reviewed by personnel at the WIM host site for confirmation 104 of approval.

If the transaction approval is confirmed, the buyer has been approved to make the requested purchase. During subsequent purchases, the buyer will be transferred directly to the purchase authorization folder for expedited transaction approval and is not required to repeat the initial credit authorization process for each purchase.

Upon transaction approval, the WIM host site then generates an email to the seller confirming transaction approval

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106. The email may further include dollar amount, shipping address, handling fees, buyer shipping account numbers, etc.

Upon receipt of the confirming email, the seller ships the order and confirms shipment 108. The confirmation of shipment is directed to an orders shipped folder at the WIM host site and includes a tracking number for the shipment. In the preferred embodiment, the buyer designates a form of shipment, and related shipping information.

In response to shipment confirmation from the seller, the WIM host site generates emails to both the buyer and the seller 110. The email to the buyer includes an invoice with a description of the goods, total amount of the order, order number and shipment tracking number. The email to the seller is the same as the email to the buyer, but additionally includes a change of title credit slip for the specified invoice, less a transaction fee due to the WIM host site. A copy of each of the buyer and seller emails is retained in an invoice folder at the WIM host site. The invoice folder is preferably a password protected folder maintained by the host site.

As noted earlier, the WIM system may also be used by sample providers as an inventory management service for private inventory. Sample providers can maintain private virtual "shelf space" on the host site which they can access from anywhere in the world using a web-enabled computer. Using techniques similar to those set forth in connection with buyer searching and sample provider searching of the wish list, sample providers can use the search engine of the WIM system to search within, review and update their own inventories, all at minimal cost to the sample providers.

The foregoing descriptions and drawings should be considered as illustrative only of the principles of the invention. The invention may be configured in a number of ways, using a variety of software and hardware, and is not limited by the configuration of the preferred embodiment. Numerous applications of the present invention will readily occur to those skilled in the art. For example, the web-integrated inventory management system may be used to manage other types of inventory or as a clearinghouse for many kinds of specialty and non-specialty items. Therefore, it is not desired to limit the invention to the specific examples disclosed or the exact configuration and operation shown and described. Rather, all suitable modifications and equivalents may be resorted to, falling within the scope of the invention.

What is claimed is:

1. A method of implementing, with a central host site, an electronic commerce exchange for a web-integrated inventory of biological samples, the method comprising:

inputting identification information on a plurality of biological samples to a central host site inventory database, said plurality of biological samples belonging to at least one sample provider;

inputting a search request to the database for a biological sample, the search request containing specified search criteria;

searching the database for a biological sample matching the specified search criteria;

displaying a search result; and

notifying, in response to a positive search result, a potential buyer of an availability of said biological sample.

2. The method as set forth in claim 1, further comprising, in response to a negative search result, the step of:

inputting a request for the biological sample to the central host site.

3. The method as set forth in claim 1, wherein said identification information for each biological sample

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includes data corresponding to specified fields, and said specified search criteria includes data corresponding to at least one of the specified fields such that the step of searching is conducted on a field by field basis.

4. The method as set forth in claim 3, further comprising, in response to a negative search result, the step of: inputting a request for the biological sample to the central host site.

5. The method as set forth in claim 4, the step of inputting a request including inputting the specified search criteria to a wish list of desired but currently unavailable biological samples, each desired biological sample on the wish list being described by data categorized in accordance with the specified fields.

6. The method as set forth in claim 5, further comprising the steps of:

accessing a search page within the central host site;

entering, to the search page, data describing a non-inventory biological sample, the entered data categorized in accordance with the specified fields;

searching the wish list of desired but currently unavailable biological samples in the database for a desired biological sample described by data matching the entered data of the non-inventory biological sample;

displaying a wish list search result.

7. The method as set forth in claim 6, further comprising, responsive to a positive wish list search result showing a match between the desired biological sample and the non-inventory biological sample, the steps of:

inputting identification information on the non-inventory biological sample to the central host site to add the biological sample to the inventory database as a newly available biological sample;

comparing, by the central host site, the newly available biological sample to the wish list;

identifying, by the central host site, a match between the newly available biological sample and the desired biological sample; and

generating, by the central host site, an electronic message to a potential buyer notifying the potential buyer of the newly available biological sample.

8. The method as set forth in claim 7, further comprising, responsive to the electronic message to the potential buyer notifying the potential buyer of the newly available biological sample, the steps of:

requesting an availability of the newly available biological sample;

generating, by the central host site, a first electronic message to a sample provider requesting confirmation of the availability of the newly available biological sample;

receiving, by the central host site, confirmation of sample availability;

generating, by the central host site, a second electronic message to the potential buyer confirming availability of the newly available biological sample; and

initiating, through the central host site, purchase of the newly available biological sample.

9. The method as set forth in claim 8, further comprising the steps of:

receiving, by the central host site, a method of payment instruction;

granting, by the central host site, transaction approval;

generating, by the central host site, an electronic message to the sample provider confirming transaction approval;

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shipping, responsive to transaction approval, the biological sample;

receiving shipment confirmation at the central host site; generating, by the central host site, an electronic message with an invoice.

10. The method as set forth in claim 5, further comprising the steps of:

reviewing, by the central host site, newly available biological samples added to inventory;

comparing, by the central host site, the newly available biological samples to the wish list;

identifying, by the central host site, a match between at least one of the newly available biological samples and the desired biological sample; and

generating, by the central host site, an electronic message to a potential buyer notifying the potential buyer of the at least one newly available biological sample.

11. The method as set forth in claim 1, further comprising, responsive to a positive search result showing a match between a biological sample and the specified search criteria, the steps of:

generating, by the central host site, a first electronic message to a sample provider requesting confirmation of the availability of the biological sample;

receiving, by the central host site, a response to the request for confirmation;

generating, by the central host site, a second electronic message to a buyer with a status on availability of the biological sample.

12. The method as set forth in claim 1, further comprising, responsive to a positive search result showing a match between a biological sample and the specified search criteria, the steps of:

requesting an availability of the biological sample;

generating, by the central host site, a first electronic message to a sample provider requesting confirmation of the availability of the biological sample;

receiving, by the central host site, confirmation of biological sample availability;

generating, by the central host site, a second electronic message to a buyer confirming availability of the biological sample; and

initiating, through the central host site, purchase of the biological sample.

13. The method as set forth in claim 12, further comprising the steps of:

receiving, by the central host site, a method of payment instruction;

granting, by the central host site, transaction approval;

generating, by the central host site, an electronic message to the sample provider confirming transaction approval;

shipping, responsive to transaction approval, the biological sample to the buyer;

receiving shipment confirmation at the central host site;

generating, by the central host site, an electronic message to the buyer with a first invoice and an electronic message to the sample provider with a second invoice.

14. The method as set forth in claim 1, further comprising, in response to a negative search result, the steps of:

inputting the specified search criteria to a wish list of desired but currently unavailable biological samples as a new wish;

generating, by the central host site, an electronic message notifying subscribing sample providers of the new wish;

21

receiving, by the central host site, an offer from at least one subscribing sample provider of a biological sample responsive to the new wish;

generating, by the central host site, an electronic message notifying the buyer of the biological sample being offered;

generating, by the central host site, responsive to buyer acceptance of the offer, an electronic message notifying the sample provider of acceptance by the buyer;

adding the biological sample to the central host site inventory database;

generating, by the central host site, an electronic message to the buyer with the biological sample added;

initiating, through the central host site, purchase of the biological sample.

15. The method as set forth in claim 1, the step of inputting a search request including inputting a matrix and at least one sample parameter.

16. The method as set forth in claim 1, wherein the specified search criteria may include in excess of ten sample parameters, each sample parameter describing a particular characteristic of the biological sample to which the search request is directed.

17. A web-integrated inventory management system, comprising:

a central host site having a database and a search engine for accessing the database, the database containing information identifying a plurality of biological samples according to a plurality of specified data fields, said plurality of biological samples forming an inventory;

22

at least one sample provider registered with the central host site, said at least one sample provider owning biological samples listed within the inventory;

at least one buyer, said buyer accessing the central host site using a computer and searching the database with the search engine for a desired biological sample, the buyer specifying the desired sample in accordance with specified search criteria that include data corresponding to at least one of the specified fields such that the search is conducted on a field by field basis;

wherein, responsive to a positive search outcome, said central host site interfaces between an appropriate sample provider and said buyer to confirm sample availability and approve buyer credit, coordinating sample transfer from the appropriate sample provider to said buyer and effecting transfer of payment from said buyer to said appropriate sample provider.

18. The system as set forth in claim 17, said central host site further comprising a wish list of desired but currently unavailable biological samples, additions to said wish list being input by buyers following a search of the database in which no match was found between a desired sample and biological samples within the inventory.

19. The system as set forth in claim 17, wherein the specified fields include fields categorized as at least one of sample information, patient information and oncology information.

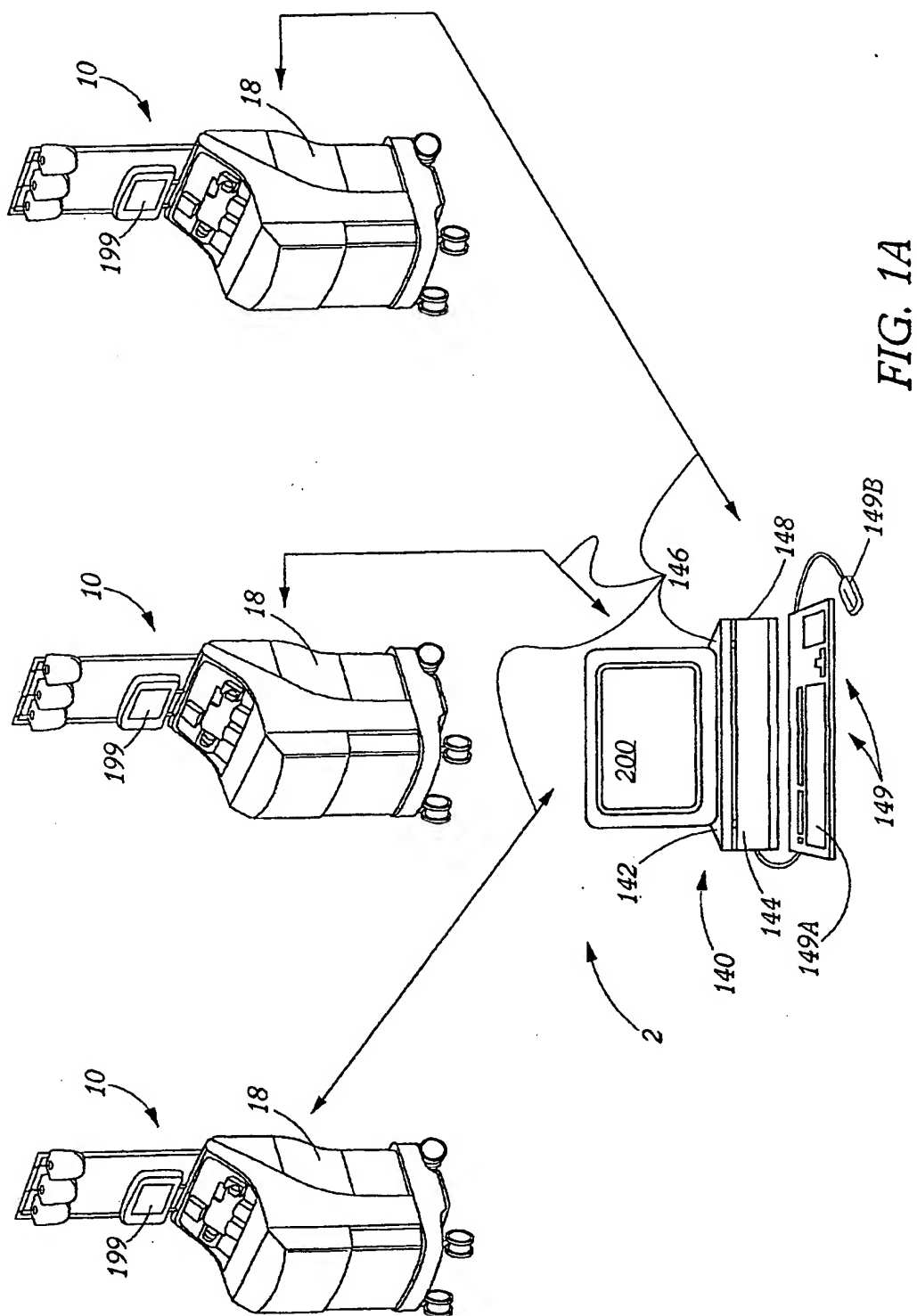
* * * * *



US 20010034614A1

(19) **United States**(12) **Patent Application Publication**
Fletcher-Haynes et al.(10) Pub. No.: **US 2001/0034614 A1**(43) Pub. Date: **Oct. 25, 2001**(54) **EXTRACORPOREAL BLOOD PROCESSING
INFORMATION MANAGEMENT SYSTEM**(76) Inventors: **Peter Fletcher-Haynes, Bailey, CO**
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60/186,123, filed on Mar. 1, 2000.**Publication Classification**(51) Int. Cl.⁷ **G06F 17/60**(52) U.S. Cl. **705/2**(57) **ABSTRACT**

A blood component collection system with manipulation and optimization capabilities. In one embodiment, process parameters are derived from an input/configured predetermined blood component yield and which is based upon the maximization of at least one process parameter. Thereafter, the blood component collection procedure is performed with these derived process control parameters. In another embodiment, process parameters are derived from an input total procedure time from a maximized value for at least one of the other process control parameters so as to maximize blood component yield in this fixed time. Thereafter, the blood component collection procedure is performed with these derived parameters.



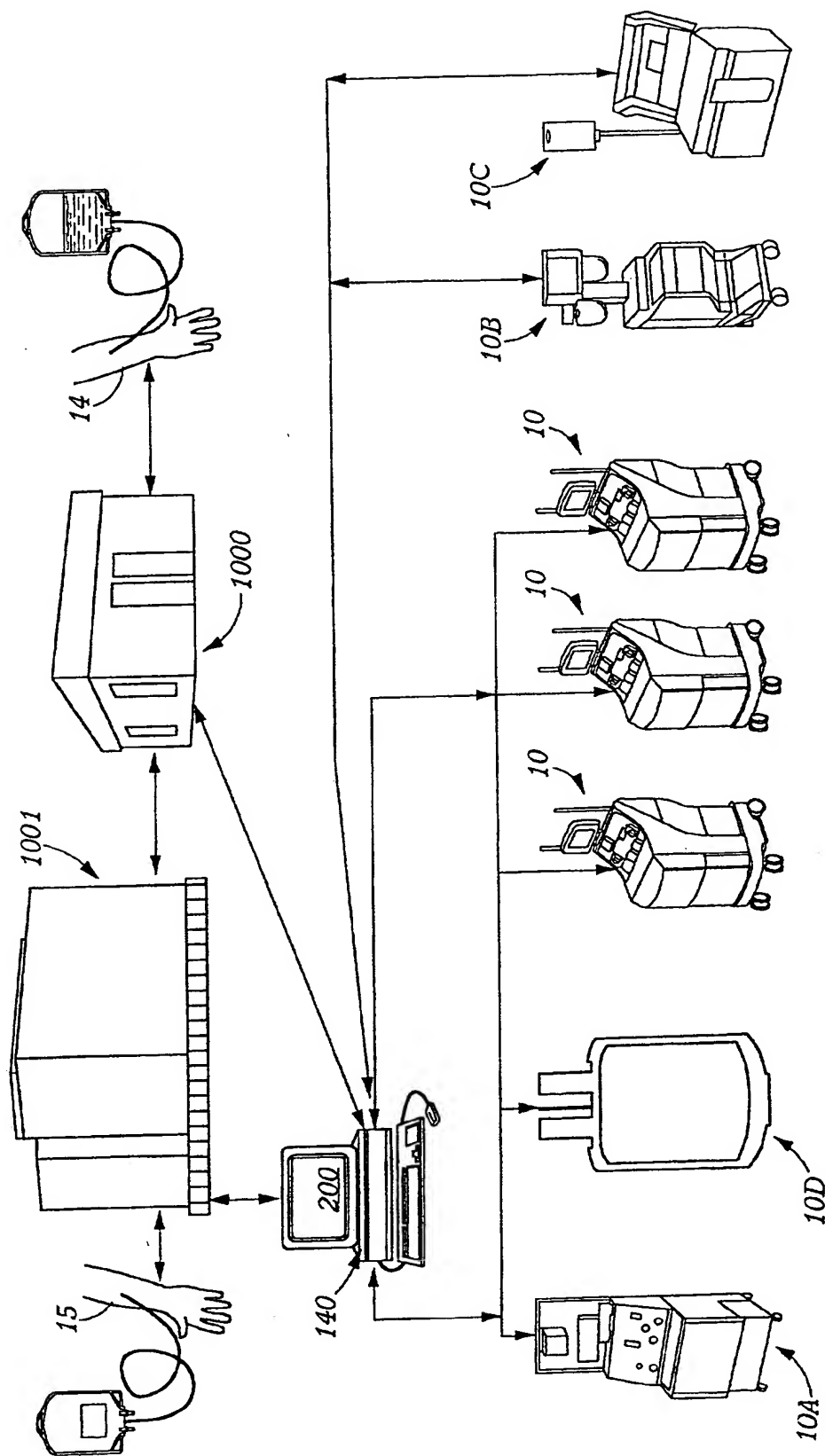
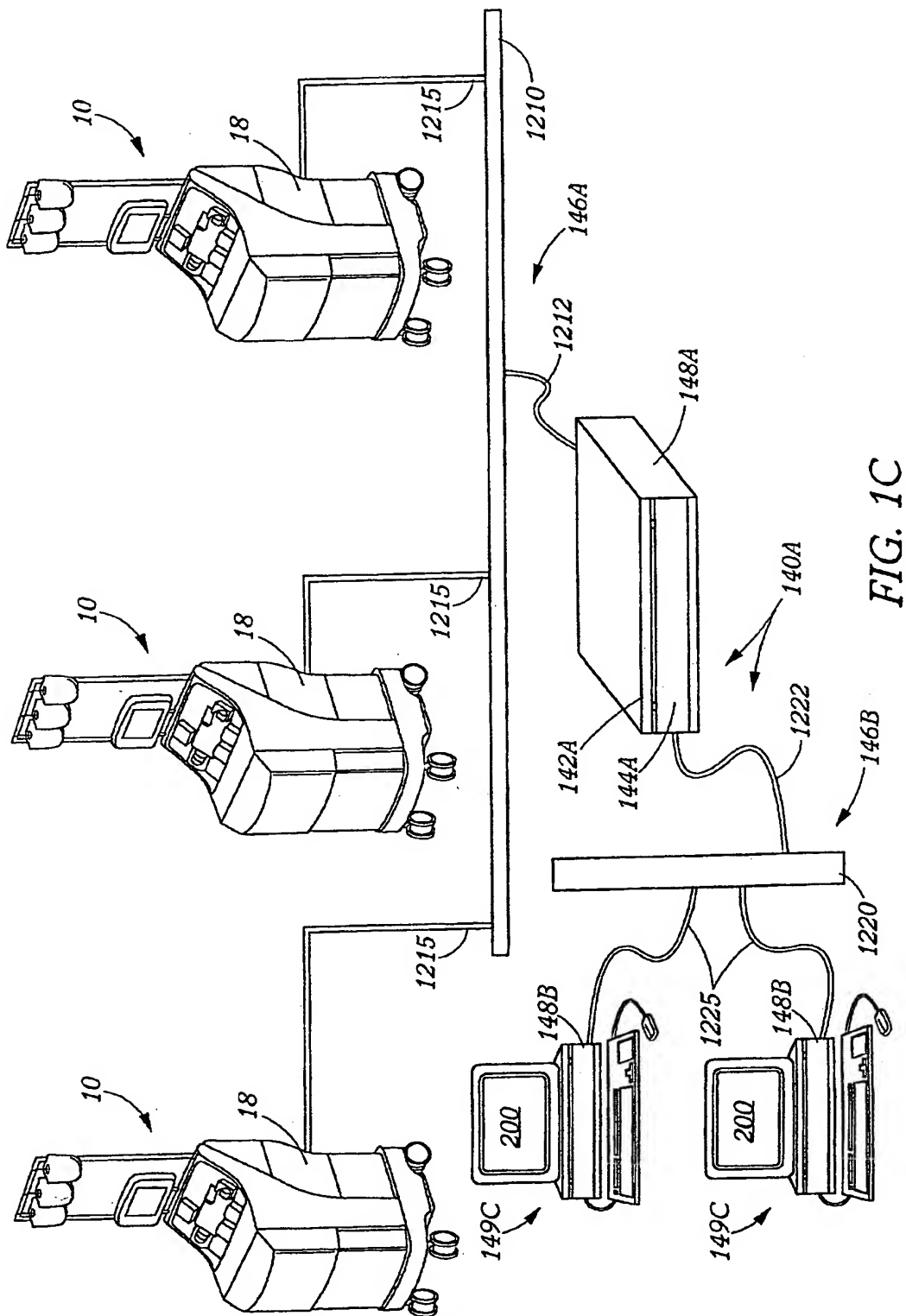


FIG. 1B



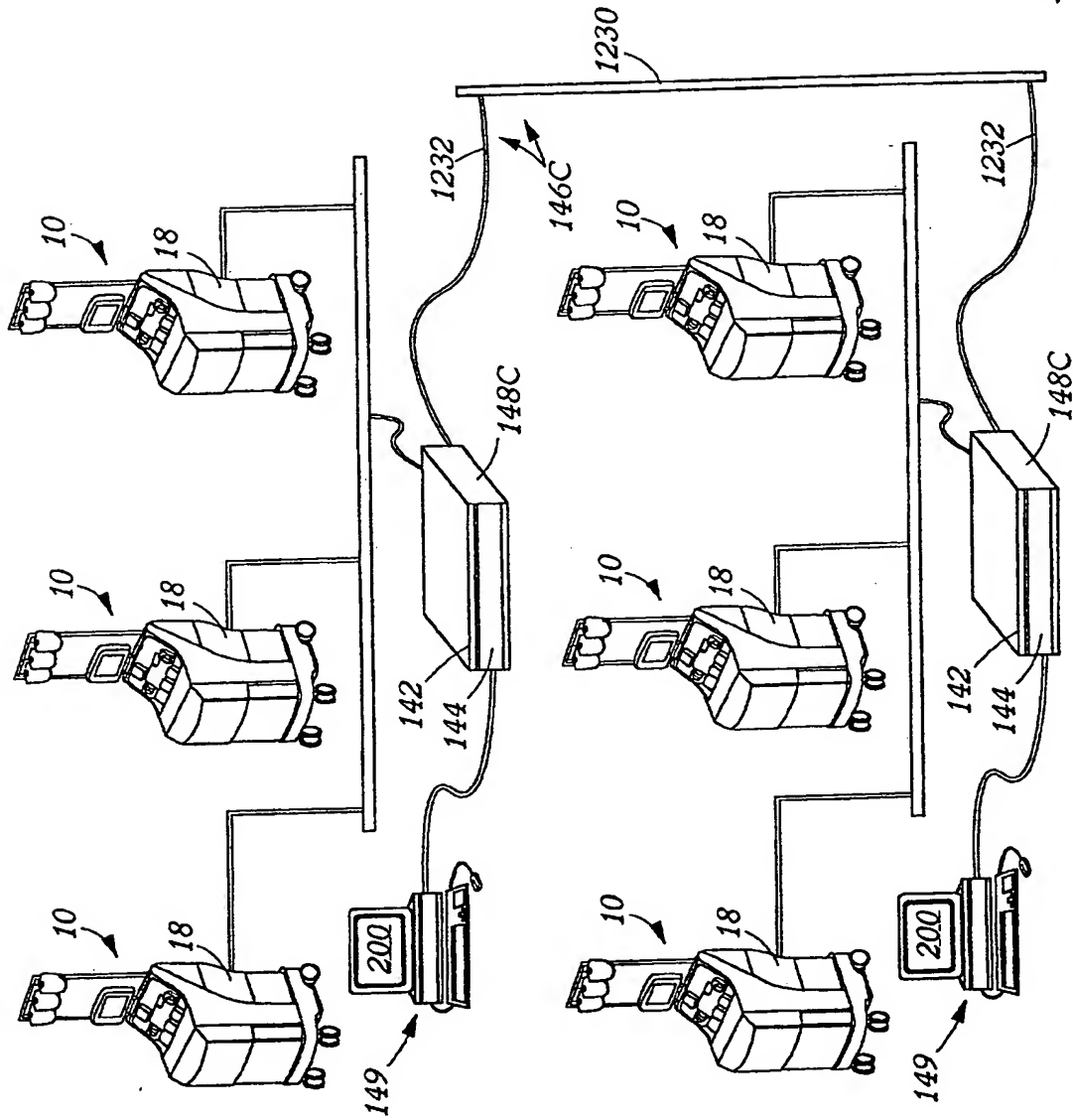


FIG. 1D

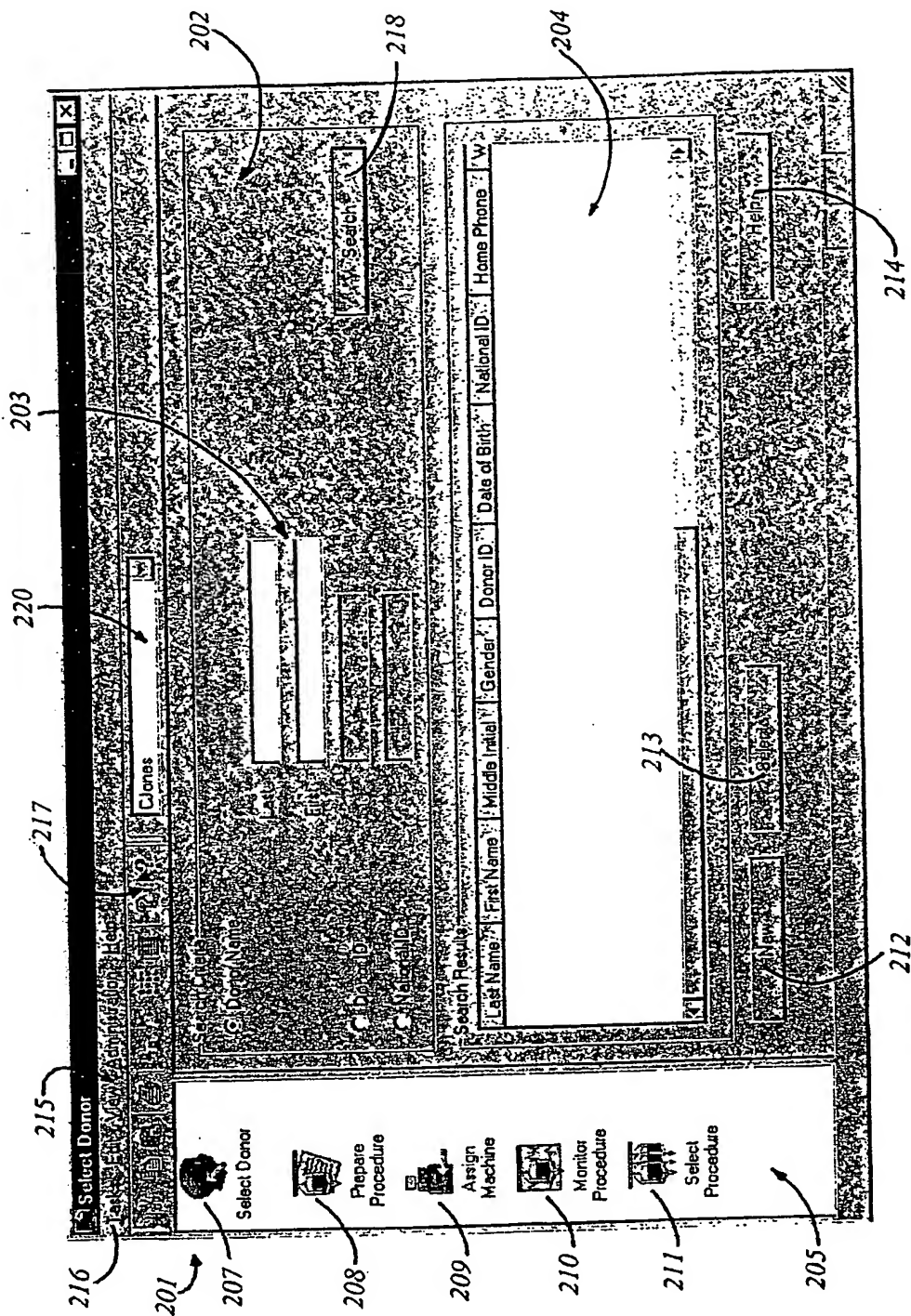


Figure 2A

Figure 1 is a screenshot of a software window titled "Donor Entry/Edit". The window contains several input fields and buttons. The "Identification" section includes fields for "First Name", "Middle Initial", "Last Name", "DOB", "DOB (MM/DD/YY)", "Edit Donor Name", and "Edit Donor ID". The "Donor Info" section includes fields for "Blood Type", "Comments", "Allergies", "Status", "Blood Loss History", and "Procedure History". The "Address" section includes fields for "National ID Number", "Address", "City", "State/Province", "Postal Code", and "Telephone Number". The "Alternate Numbers" section includes a field for "Alternate Numbers". At the bottom of the window are buttons for "Remove", "OK", "Cancel", "Apply", and "Help". Various reference numerals point to specific elements in the window: 221 points to the title bar, 222 points to the "First Name" field, 231 points to the "DOB (MM/DD/YY)" field, 224 points to the "National ID Number" field, 226 points to the "Remove" button, 227 points to the "Help" button, 228 points to the "Cancel" button, and 229 points to the "Apply" button.

Figure 2B

Donor Entry/Edit

Donor Identification Last Name First Name Middle Initial Edit Donor Name Edit Donor ID

Specialty Organ Blood Component Status Blood Loss History Specimen History

Gender: ☐ Female ☐ Male

Date of Birth: 4/5/35

Blood Background: White

Update Picture Apply Cancel Help

241

230

229

[illegible]

Figure 2D

221

Donor Entry/Edit

261

Identification

First Name Denise

Middle Initial

Last Name

Salvatore

Donor ID 559414

Edit Donor Name

Edit Donor ID

Demographics

General

History

Comments

Allogeneic

Status

Blood Loss History

Procedure History

263

<< 12/6/99 10:23:16 AM Kim Pemberton >> Denise likes Tums during her procedure.

262

Add Comment

230

Remove

OK

Cancel

Apply

Help

229

Figure 2E

271

Donor Entry/Edit

ID No.

First Name

Middle Initial

Last Name

Sex

DOB

SSN

Blood Type

Allergy

Comments

Status

Blood Loss History

Procedure History

Donor Allergy

Donor Allergy Comment

Add Allergy

Remove Allergy

Add Comment

Remove Comment

OK

Cancel

Apply

Help

12/13/99 2:02:07 PM Kim Pemberton

230

229

Figure 2F

<input type="button" value="New"/> <input type="button" value="Find"/> <input type="button" value="Print"/> <input type="button" value="Exit"/>	
<input type="button" value="Back"/> <input type="button" value="Forward"/> <input type="button" value="History"/> <input type="button" value="Status"/> <input type="button" value="Labels"/> <input type="button" value="History"/> <input type="button" value="Procedure History"/>	
Identification Last Name: <input type="text"/>	Identification First Name: <input type="text"/>
Salvo: <input type="text"/>	Gender: <input type="text"/>
Donor ID: <input type="text"/>	Donor ID: <input type="text"/>
Donor Status: <input type="text"/>	Donor Status: <input type="text"/>
Donor Category: <input type="text"/>	Donor Category: <input type="text"/>
Last Visit Date: <input type="text"/>	Last Visit Date: <input type="text"/>
Last Procedure Date: <input type="text"/>	Last Procedure Date: <input type="text"/>
Last Contact Date: <input type="text"/>	Last Contact Date: <input type="text"/>
Whole Blood Donor: <input type="text"/>	Whole Blood Donor: <input type="text"/>
Donor Status: <input type="text"/>	Donor Status: <input type="text"/>
Donor ID: <input type="text"/>	Donor ID: <input type="text"/>
<input type="button" value="New"/> <input type="button" value="Find"/> <input type="button" value="Print"/> <input type="button" value="Exit"/>	<input type="button" value="Back"/> <input type="button" value="Forward"/> <input type="button" value="History"/> <input type="button" value="Status"/> <input type="button" value="Labels"/> <input type="button" value="History"/> <input type="button" value="Procedure History"/>

Figure 2G

221

291

Donor Entry/Edit

Donor Identification

Last Name First Name Middle Initial

Selzer Denise

Donor ID 559741

Edit Donor Name Edit Donor ID

Demographics General History Comments Allergies Status Blood Loss History Procedure History

12 Month History

Total Blood Loss 20

Procedure Date	Product RBC	Sample RBC	Residual RBC	Other RBC	Product Plasma
2/2/99	0	0	0	0	0
2/4/99	0	0	0	0	0
12/3/99	0	0	0	0	0
12/6/99	0	0	0	0	0
12/6/99	0	0	0	0	0
12/6/99	0	0	0	0	0
12/7/99	0	0	0	0	0
12/7/99	0	0	0	0	0

Remove OK Cancel Apply Help

Figure 2H

Donor Entry/Edit

Donor ID: [] Identification: []

Last Name: [] First Name: [] Middle Initial: []

Suffix: [] Donor Sex: [] Donor Age: []

Donor ID: [] Donor ID: []

Edit Donor Name [] Edit Donor ID []

General Information Comments Allergies Status Blood Loss History Procedure History

Procedure Date	Platelet Yield	Plasma Volume	RBC Volume
12/2/99	0	0	0
2/4/99	0	0	0
12/3/99	0	0	0
12/6/99	0	0	0
12/6/99	0	0	0
12/6/99	0	0	0
12/7/99	0	0	0
12/7/99	0	0	0
12/8/99	0	0	0
12/8/99	0	0	0

Remove [] OK [] Cancel [] Apply [] Help []

Figure 2I

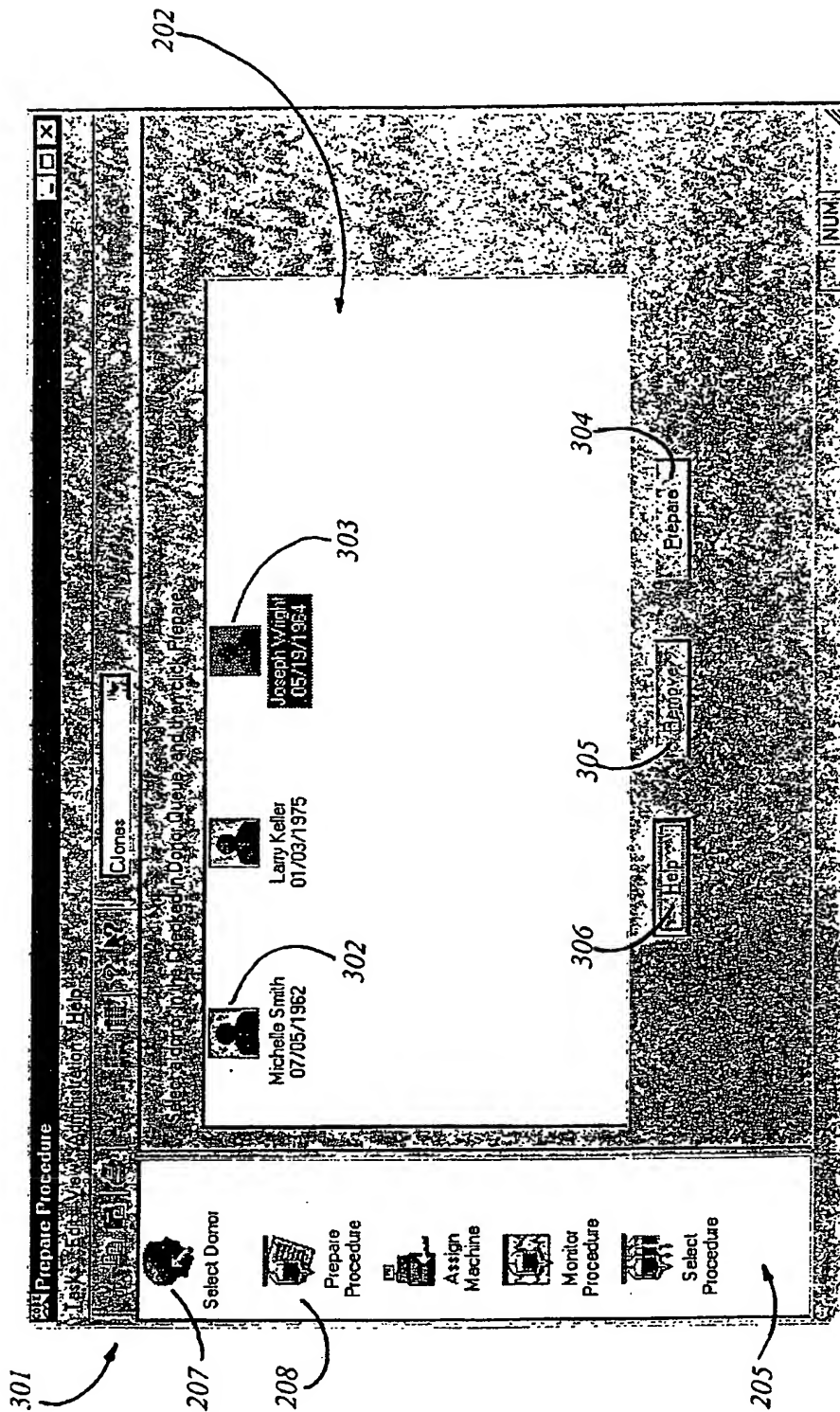


Figure 3A

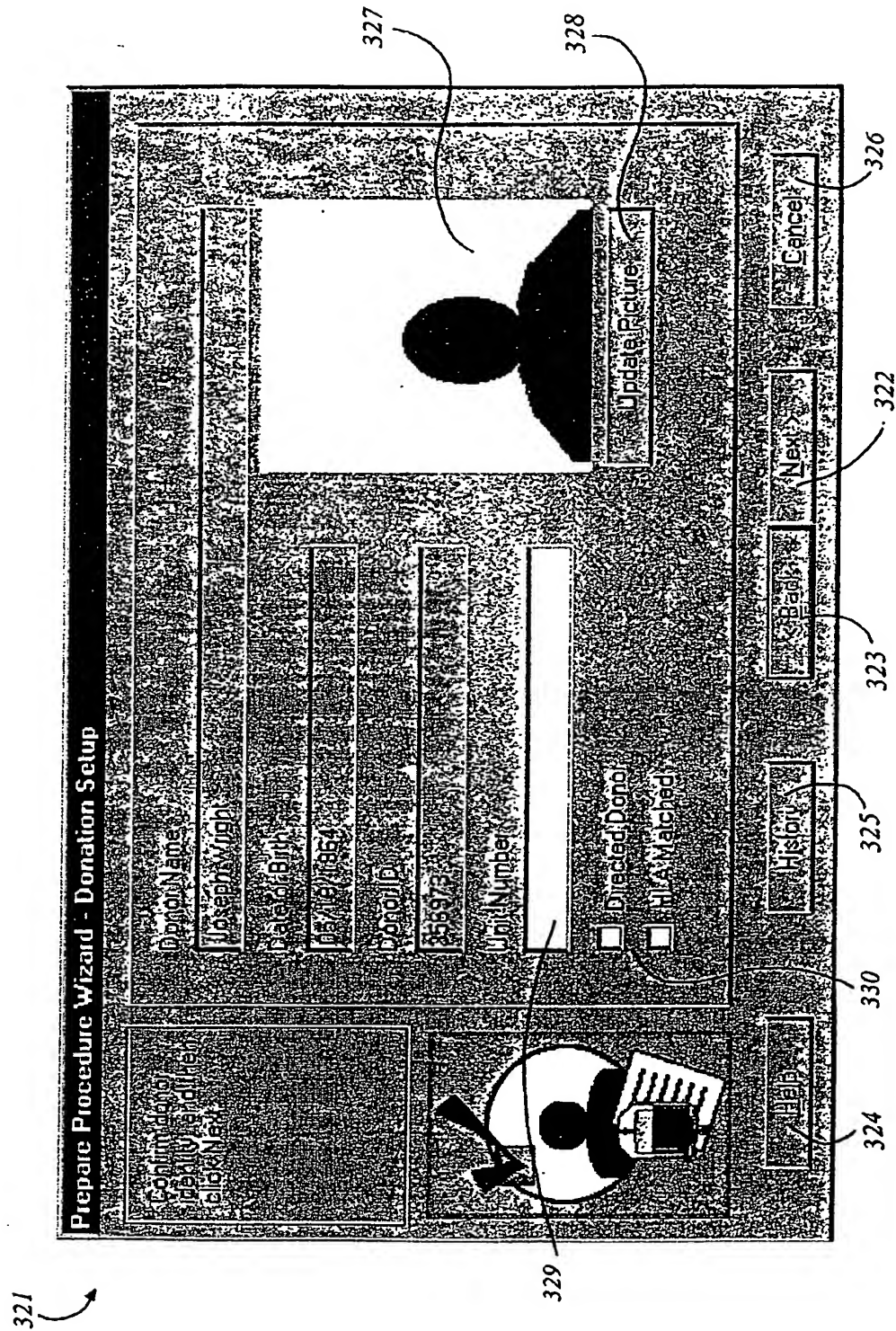


Figure 3B

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332

Prepare Procedure Wizard - Donor Information

Enter donor's
spatula and
test stick

Donor Name
Please type in
Donor's name

Gender
☒ Male
☐ Female

Height
6'03" ft/in

Weight
235 lb

BV
6572 ml

Blood Type
O+

Hematocrit
48

Platelet Count
244 x 1000/ μ l

Temperature
98

Blood Pressure
110 mm Hg

Pulse
60 beats/min

History

Help

Back

Next

Cancel

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Figure 3C

341

Prepare Procedure Wizard - Select Products and Configuration

Selected Products and Configuration and Parameters

Donor Name: [Random] [Donor]

Installed Products:

- ☒ Platelet
- ☒ Plasma
- ☒ Red Blood Cells

Configuration:

Focus List:

Platelet/Red Blood Cells

Machine Configuration:

Novice Donor Configuration

Help Back Next Cancel

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Figure 3D

351

Prepare Procedure Wizard - Target Procedure

Confirm the target procedure and then click Finish

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1622

Procedure Adjustments

Procedure Time: Time (min)

Tubing Set Types:

☒ Grey ☒ White ☒ Black

361

Figure 3F

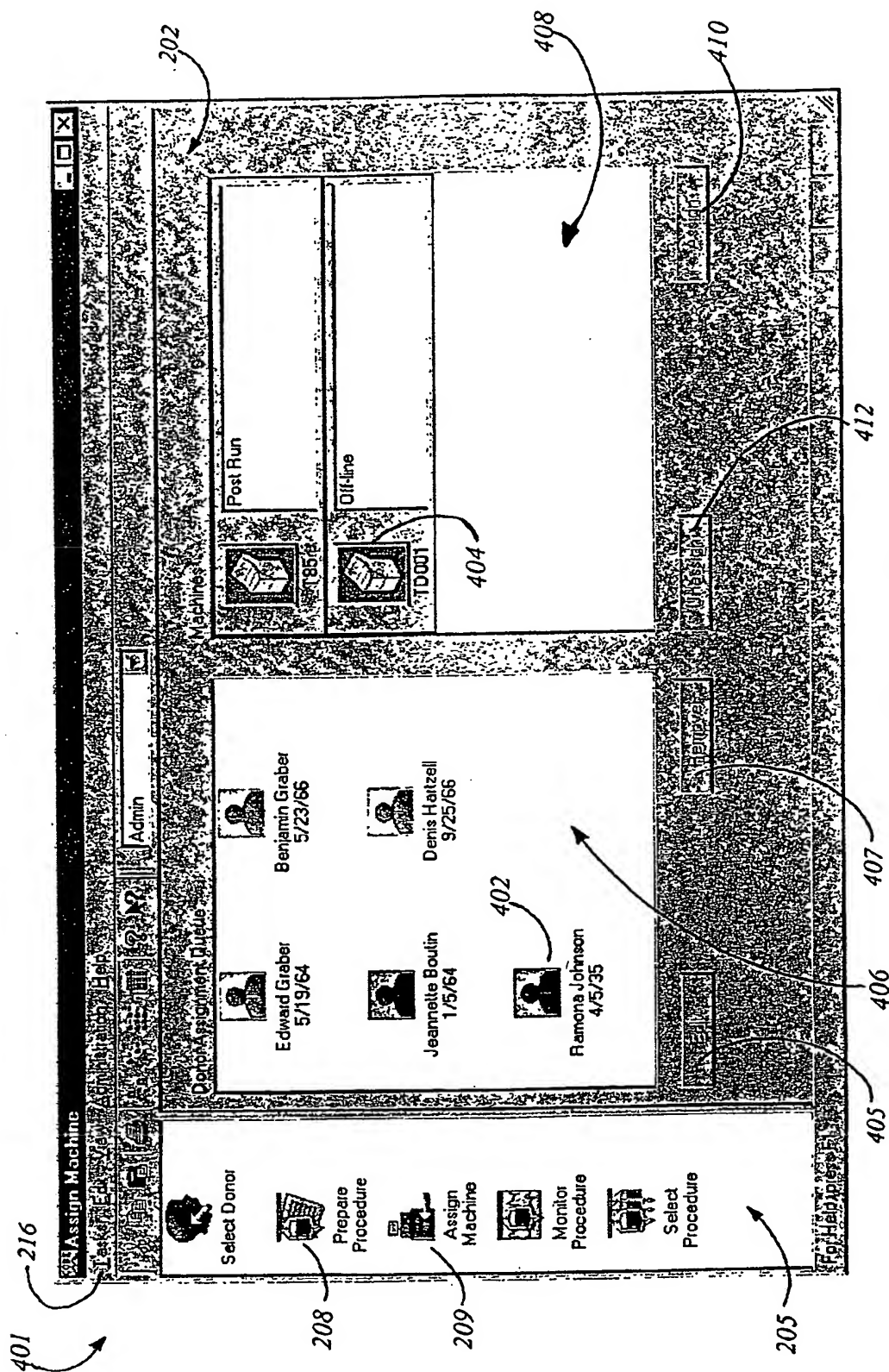


Figure 4A

load

info

prepare donate

unload

DONOR NAME AND DATE OF BIRTH
Joseph Wright 05/19/64

gender	male
height	6 ft 3 in
weight	235 lbs
tbv	6579 ml
blood type	O+
hematocrit	48%
platelet precount	244x1000

confirm info

confirm info

Figure 4B

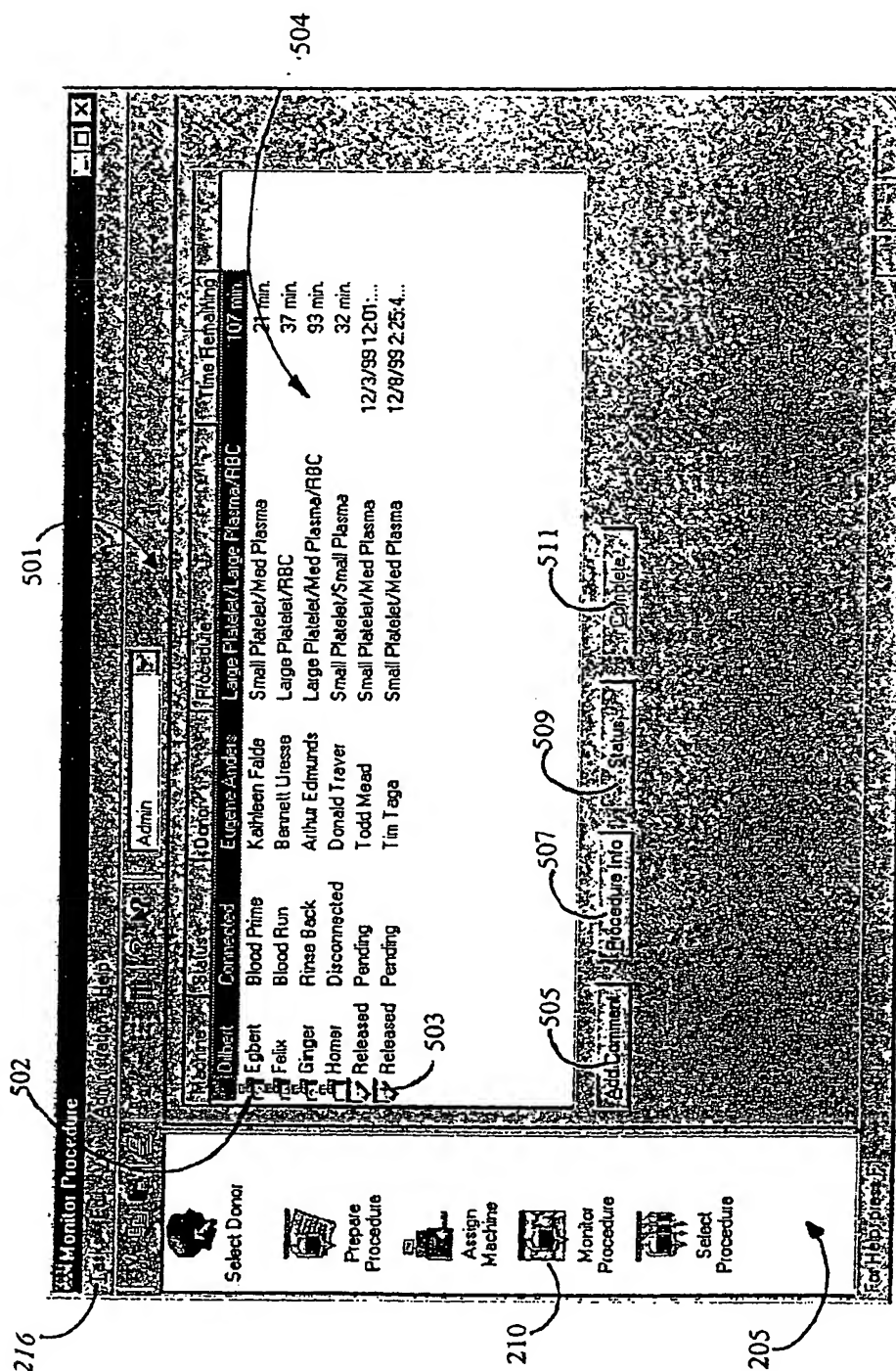


Figure 5A

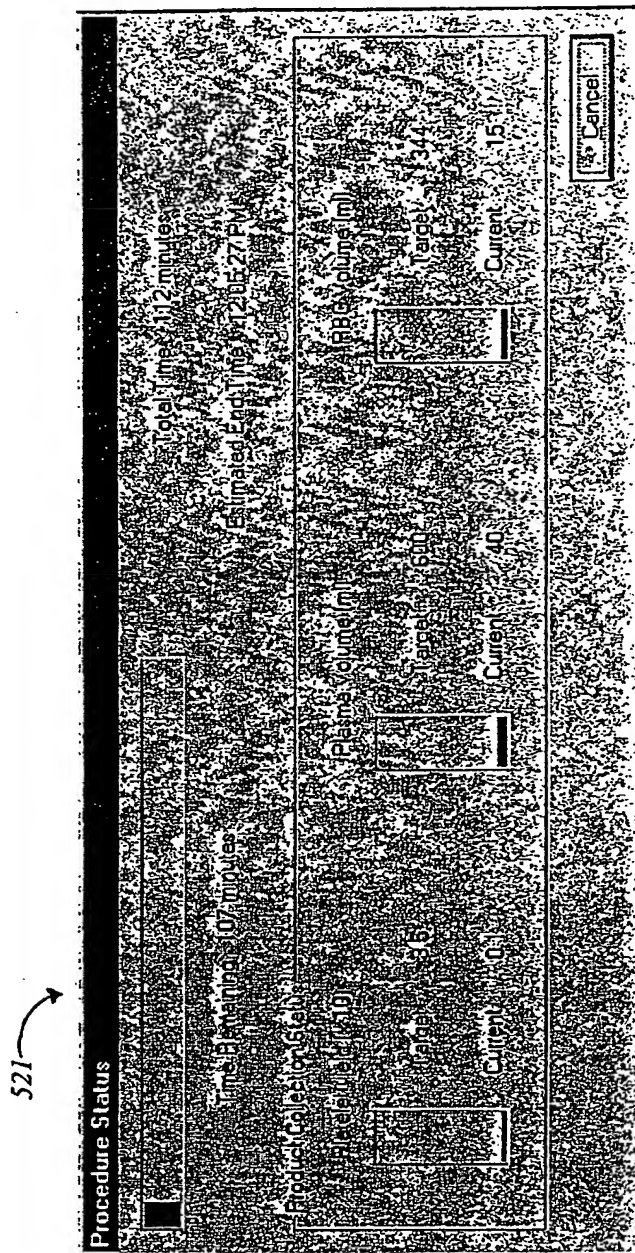


Figure 5B

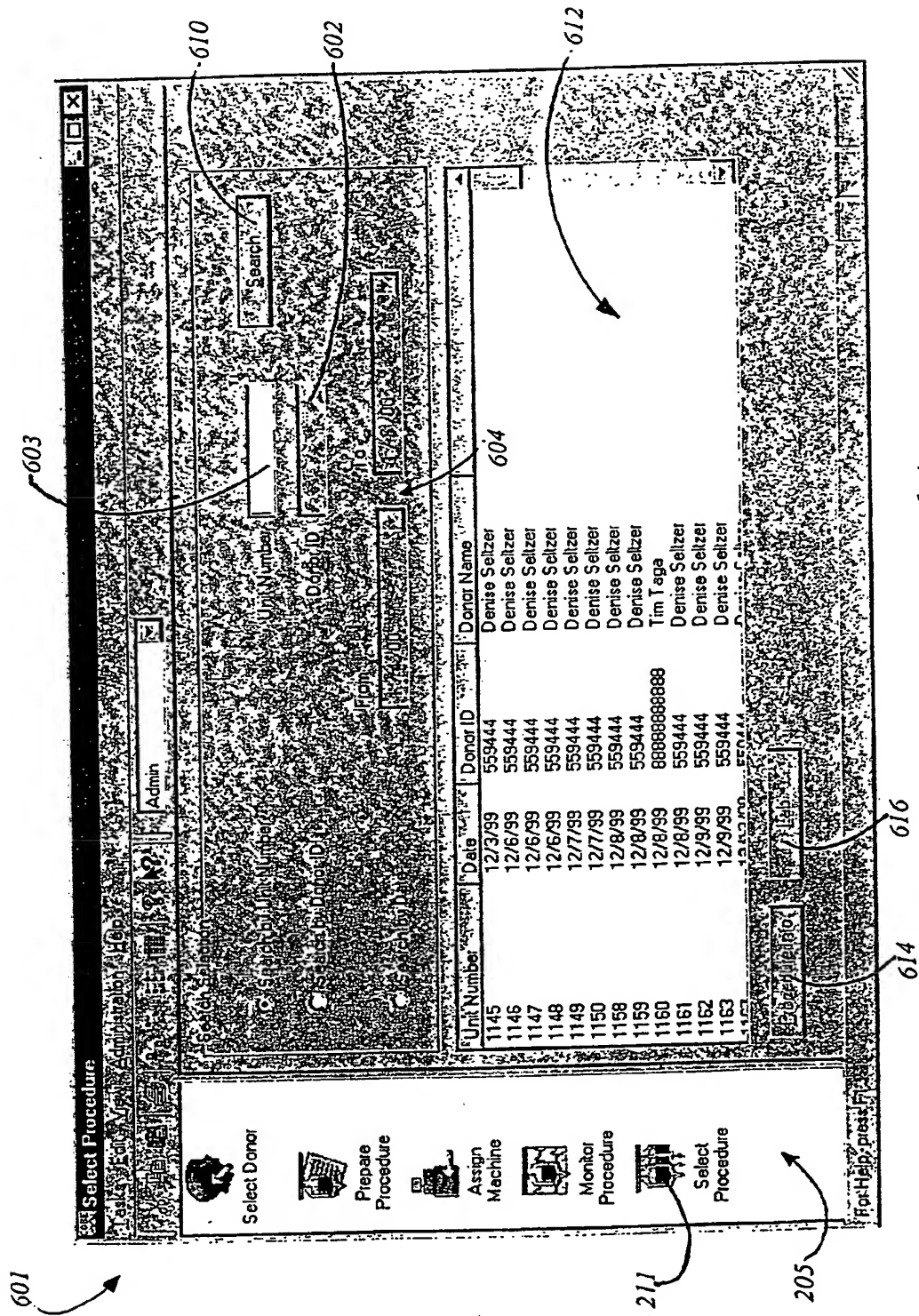
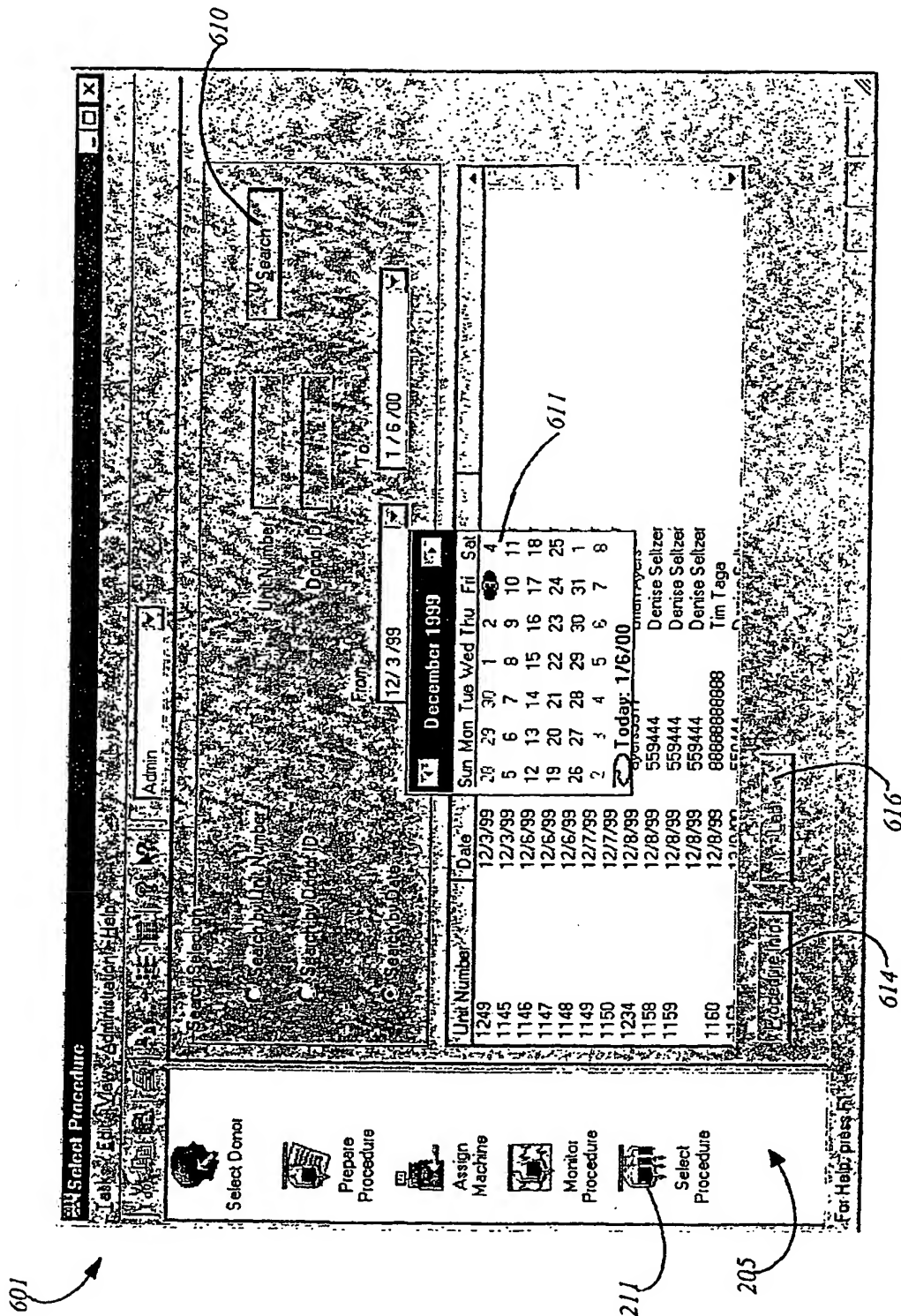


Figure 6A



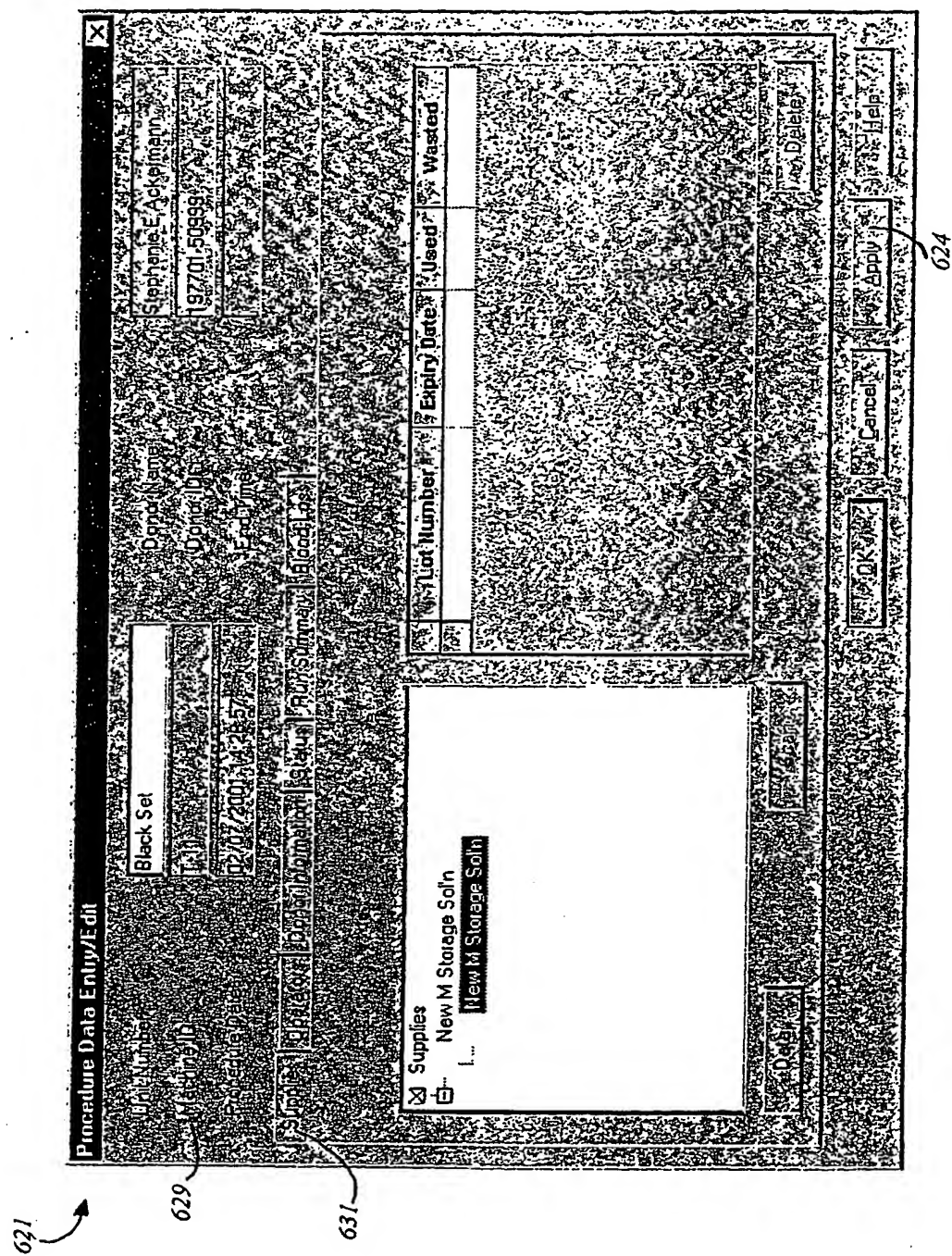


Figure 6C

Finalize Procedure Information

Unit Number: 00010 Patient ID: 00010
 Machine ID: 00010 Patient Name: Eugene H. Anders
 Procedure ID: 00010 Date: 09-10-AM

Supplies: 00010 Procedure Status: 00010 Procedure Log: 00010 Procedure Log: 00010

Operator ID	Operator Name
Bill Sweet	Bill Sweet
Alex Murillo	Alex Murillo
System Administrator	System Administrator

Help Apply OK Cancel

Figure 6D

Finalize Procedure Information

Patient ID: 4835 Patient Name: Eugene H. Anders DOB: 02/10/1959 Gender: M Height: 5'10" Weight: 160 lbs Blood Type: A Blood Status: Unknown H.A. Status: Negative Hemoglobin: 12.5 Platelets: 250,000

Procedure Date: 02/07/1999 Procedure Time: 10:00 AM Procedure Location: Surgery Procedure Log: Run Summary Good Log: Good Log

Help Apply OK Cancel

Figure 6E

[illegible]

Figure 6F

621

671

624

622

Finalize Procedure Information

Unit Number 1833	Donor ID 1833	Donor Name Eugene H. Arde...
Machine ID 102703	Donor Name 1833	Donor Name 1833
Procedure Code 102703	Donor Name 1833	Donor Name 1833

Supplies: ☐ Platelets ☐ Red Cell Status ☐ Procedure Log ☐ Run Summary ☐ Blood Loss

Procedure Name
Large Platelet/Large Plasma/RBC

Procedure Date
02/03/1999 8:30:00 AM Bill Sweat >> A102 - Centrifuge stopped due to donor

Help Apply OK Cancel Comment

Figure 6G

[illegible]

Figure 6H

[illegible]

Figure 61

[illegible]

Figure 6J

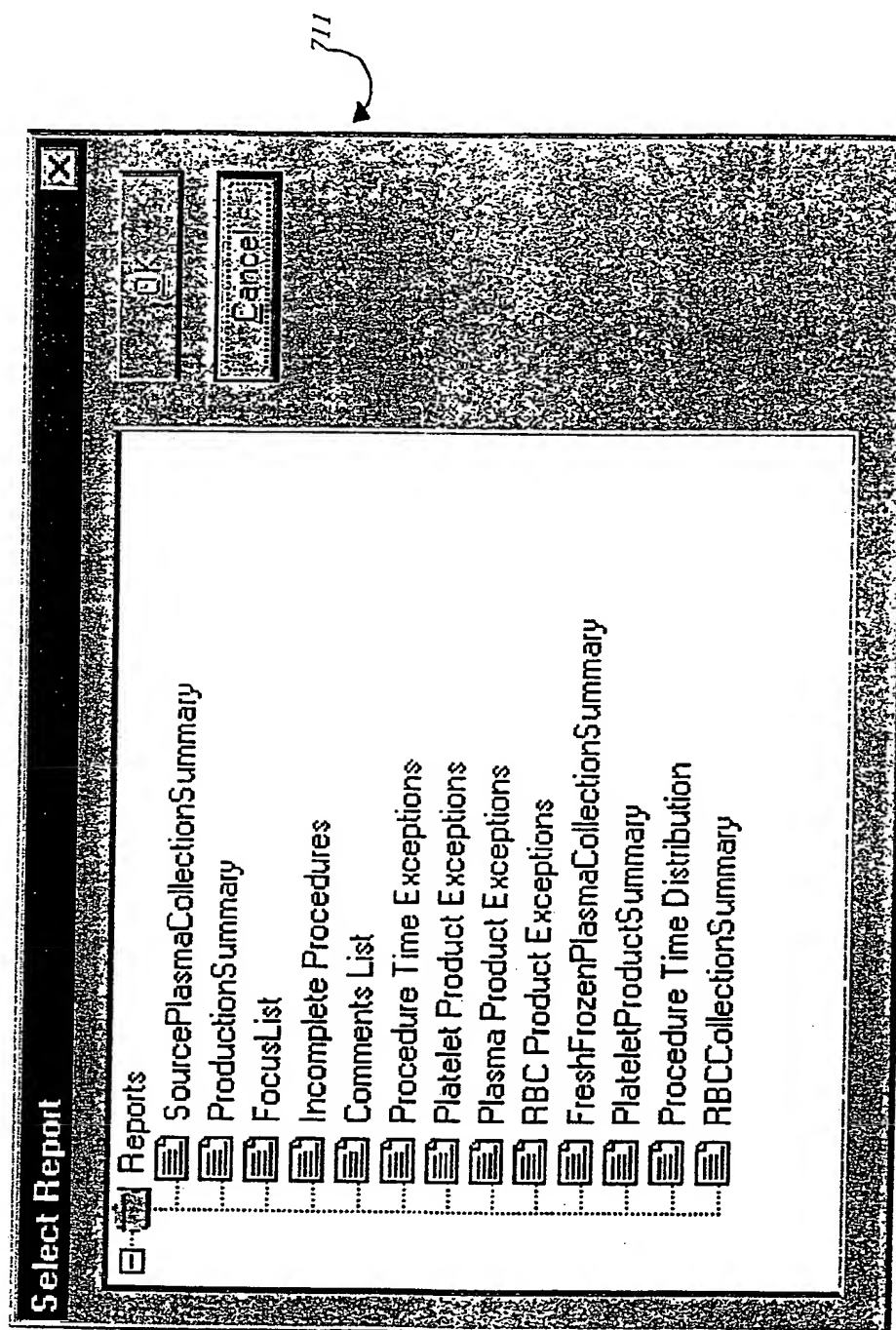


Figure 6K

721

Plasma Product Exceptions: Runtime Parameter Form

Start Date: 01/31/01

End Date: 02/28/01

Production Label: 0

Machine Type: All

Machine ID: All

OK Cancel Help

Figure 6L

731

Procedure Record

Unit Number : 1	Facility Name : Gamblro BCT	Date : 09/20/00	Machine Type : Test
Donor Name : Grace K Hui	Donor ID : 1	Date of Birth : 10/02/1980	Machine ID : grace
Height : 120 cm	Weight : 50 kg	Gender : Female	Blood Type : O+
Blood Pressure : 120/80 mmHg	Pulse : 90 beats/min	Temperature : 98.5 C	TBV : 8500 ml
Pre-run Hemoglobin : 15 g/dL	Platelet Pre-Count : 4.0 x1000/ μ L	Access : right	Return : left
Post-run Hemoglobin : 15 g/dL	Platelet Post-count : 4.0 x1000/ μ L		
Procedure Targets : RBC/PLT 15 (300 min.)			
Volume (ml) :	Platelet	Plasma	Whole Blood
Yield (E11) or Packed Cell Vol (ml) :	300	300	500
Conc. \times 1000/ μ L or Collect Hct (%):	3.6		400
End of Run Summary :			
Procedural			
Procedure Time (minutes) :	350	Blood Volume Processed (ml) :	8520
Total AC Used (ml) :	20	AC to Donor (ml) :	30
Replacement Fluid Volume (ml) :	50		
Final Product Predictions :			
Volume (ml) :	Platelet	Plasma	Whole Blood
Yield (E11) or Packed Cell Vol (ml) :	300	100	500
Conc. \times 1000/ μ L or Collect Hct (%):	3.5		200
AC in product (ml) :	1167	20	80
	10		20

Figure 6M

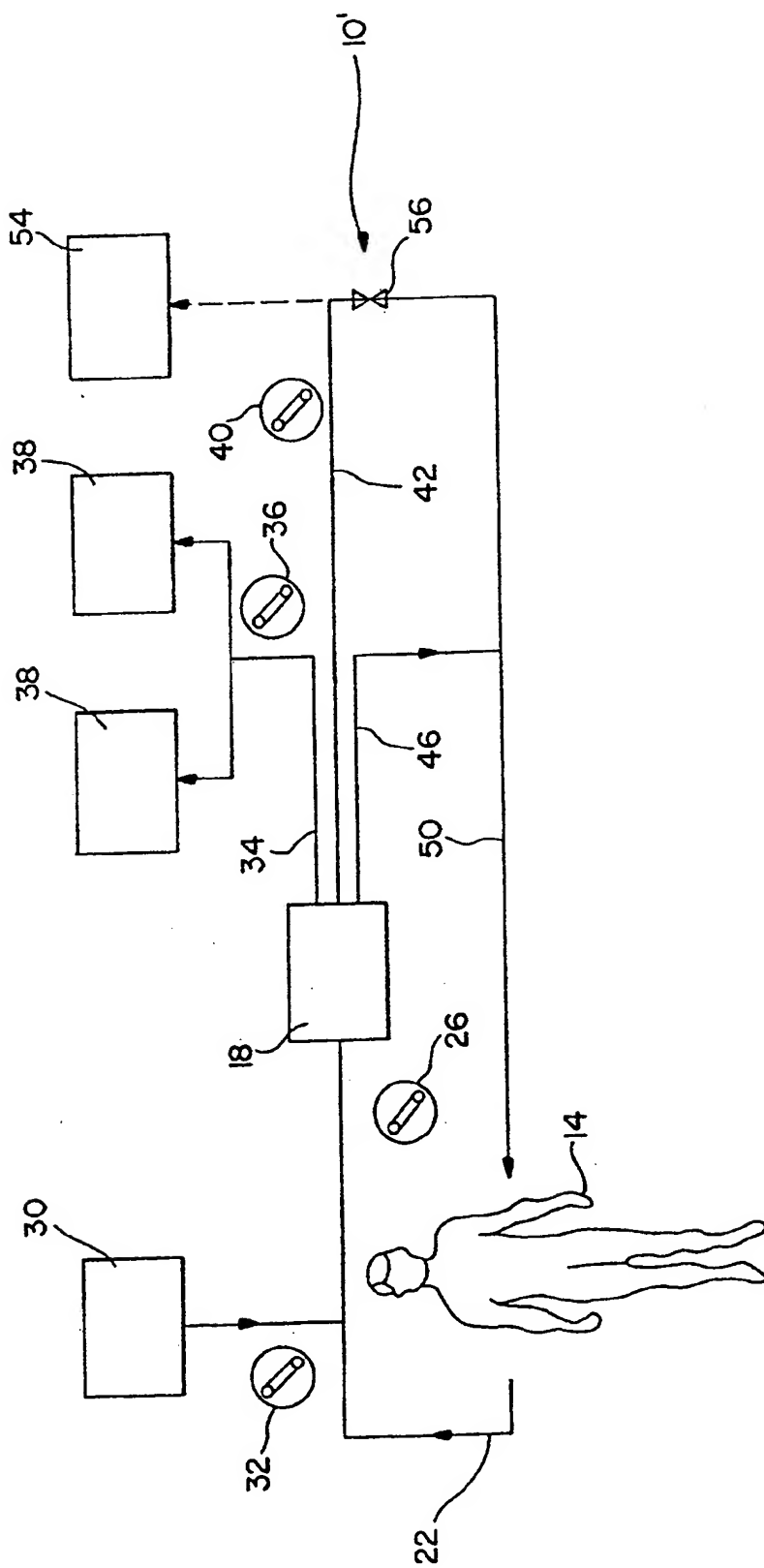


Figure 7A

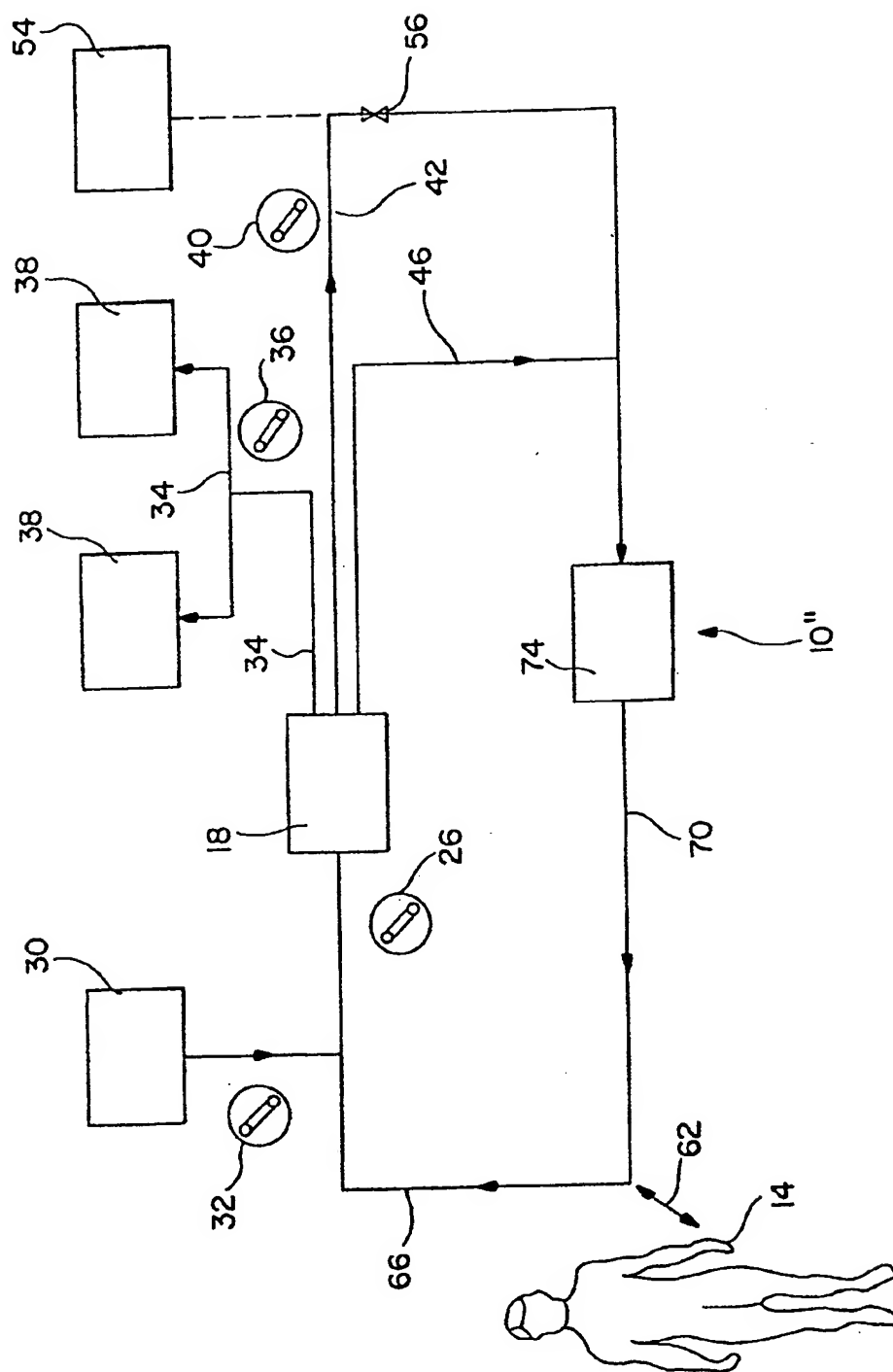


Figure 7B

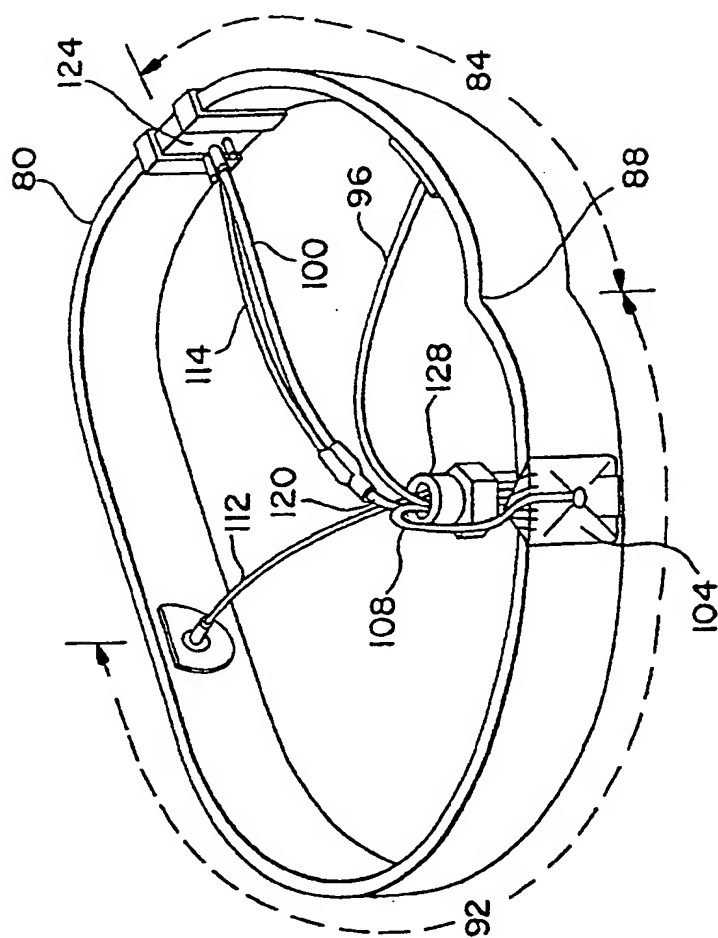


Figure 8A

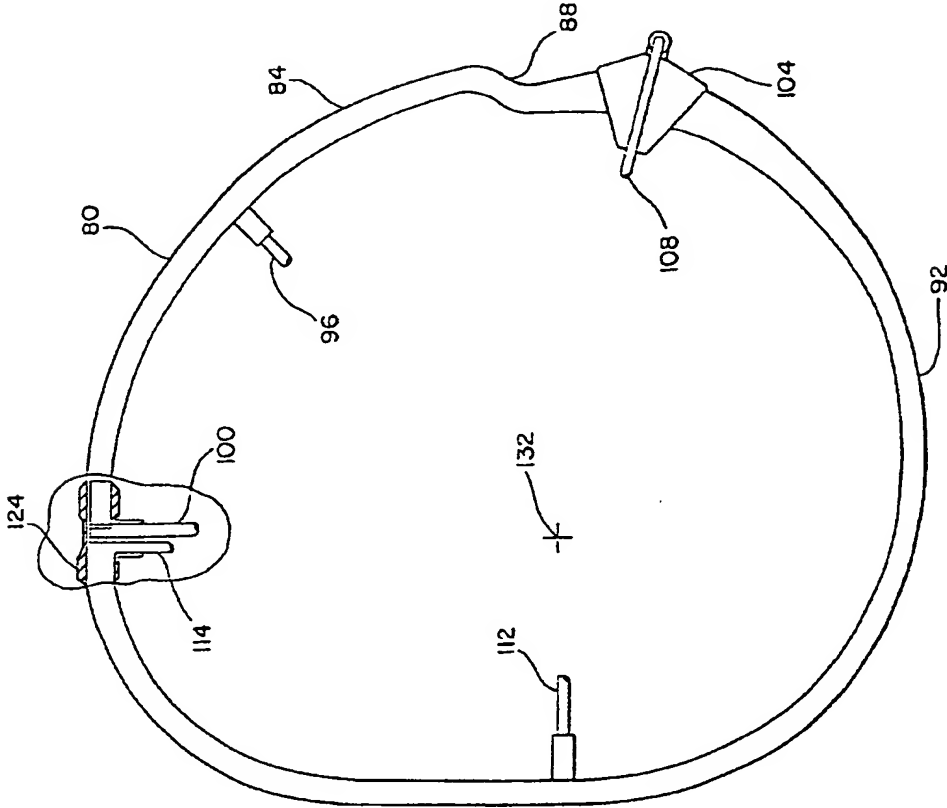


Figure 8B

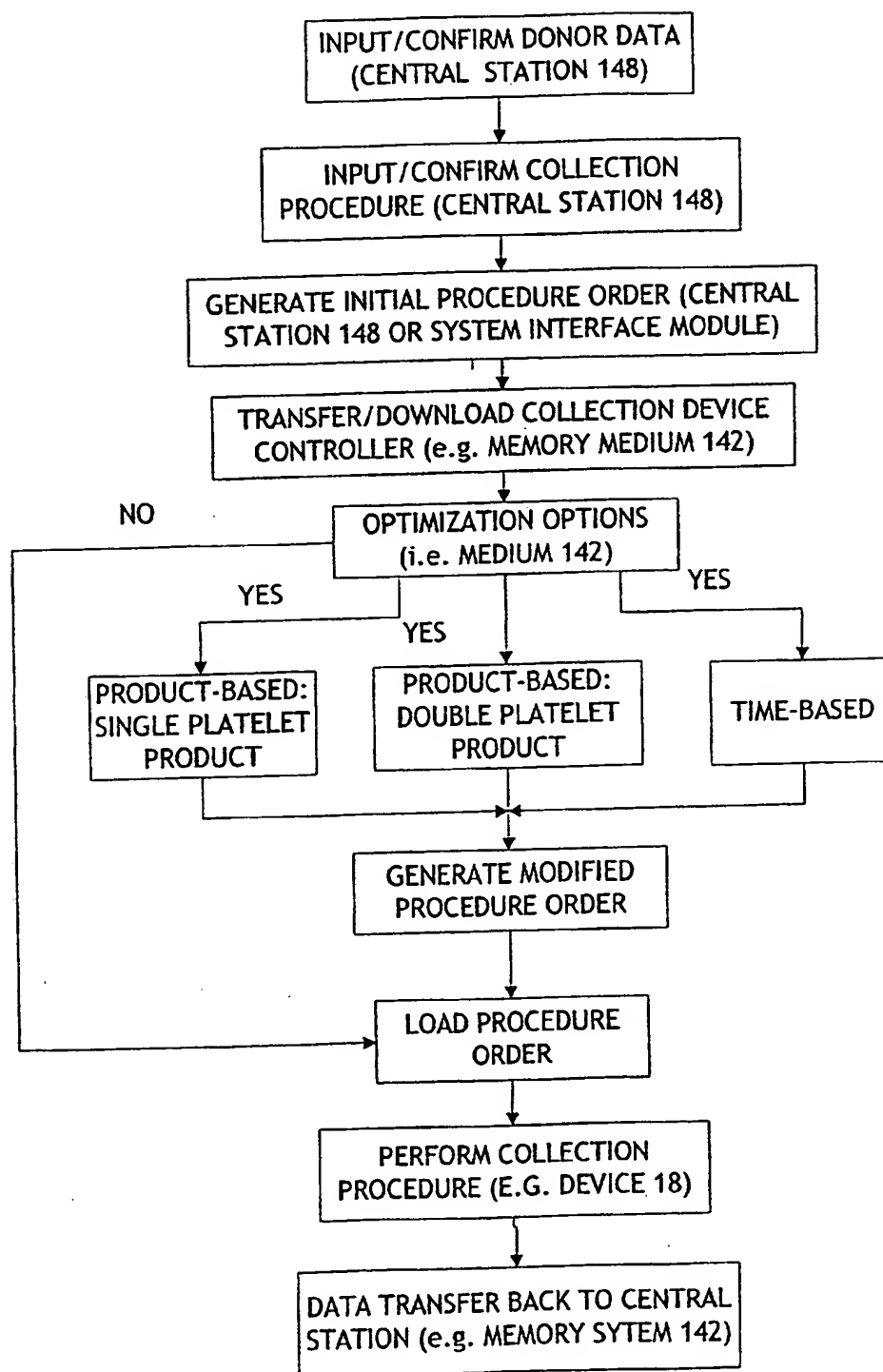


Figure 9A

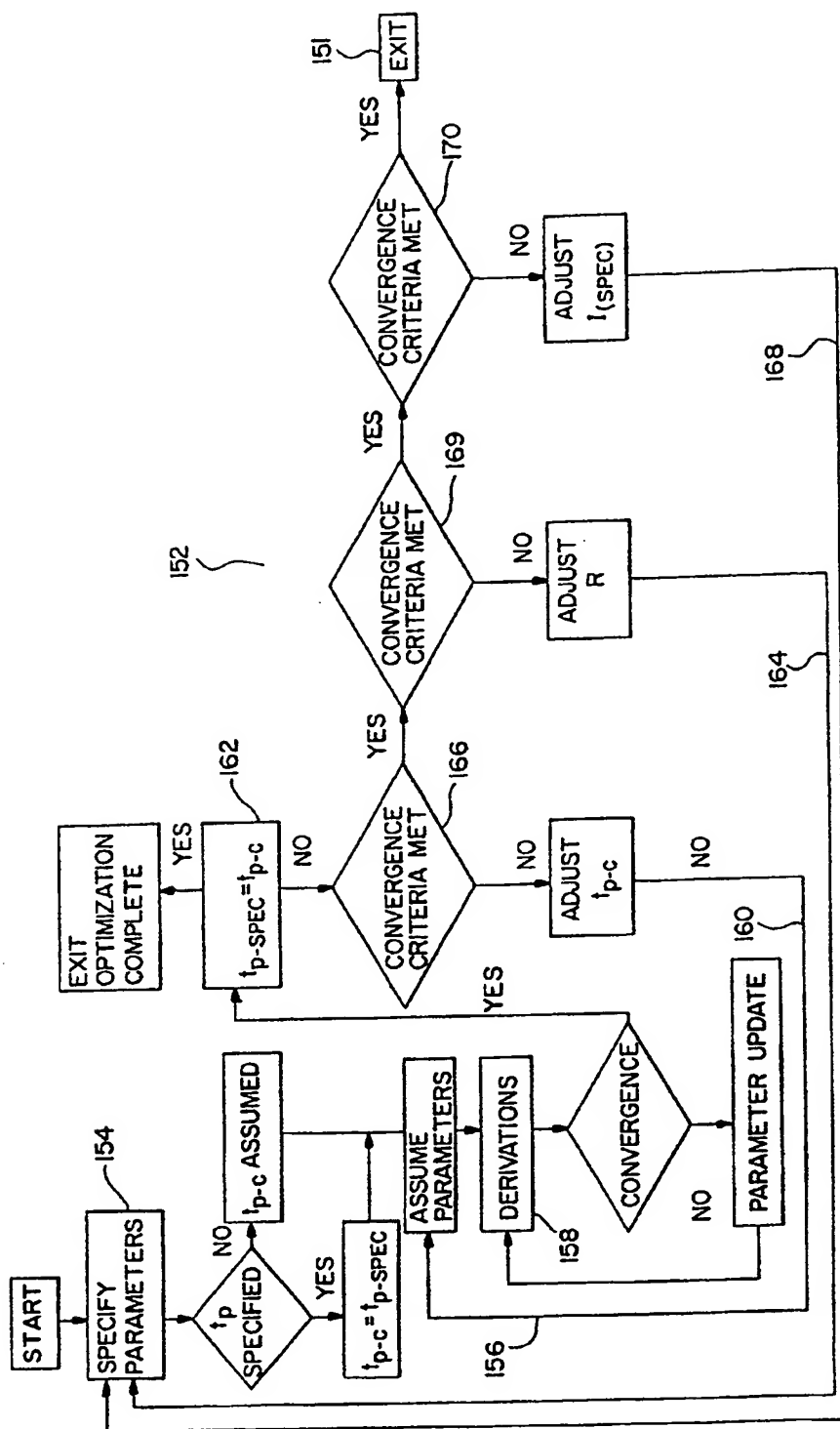


Figure 9B

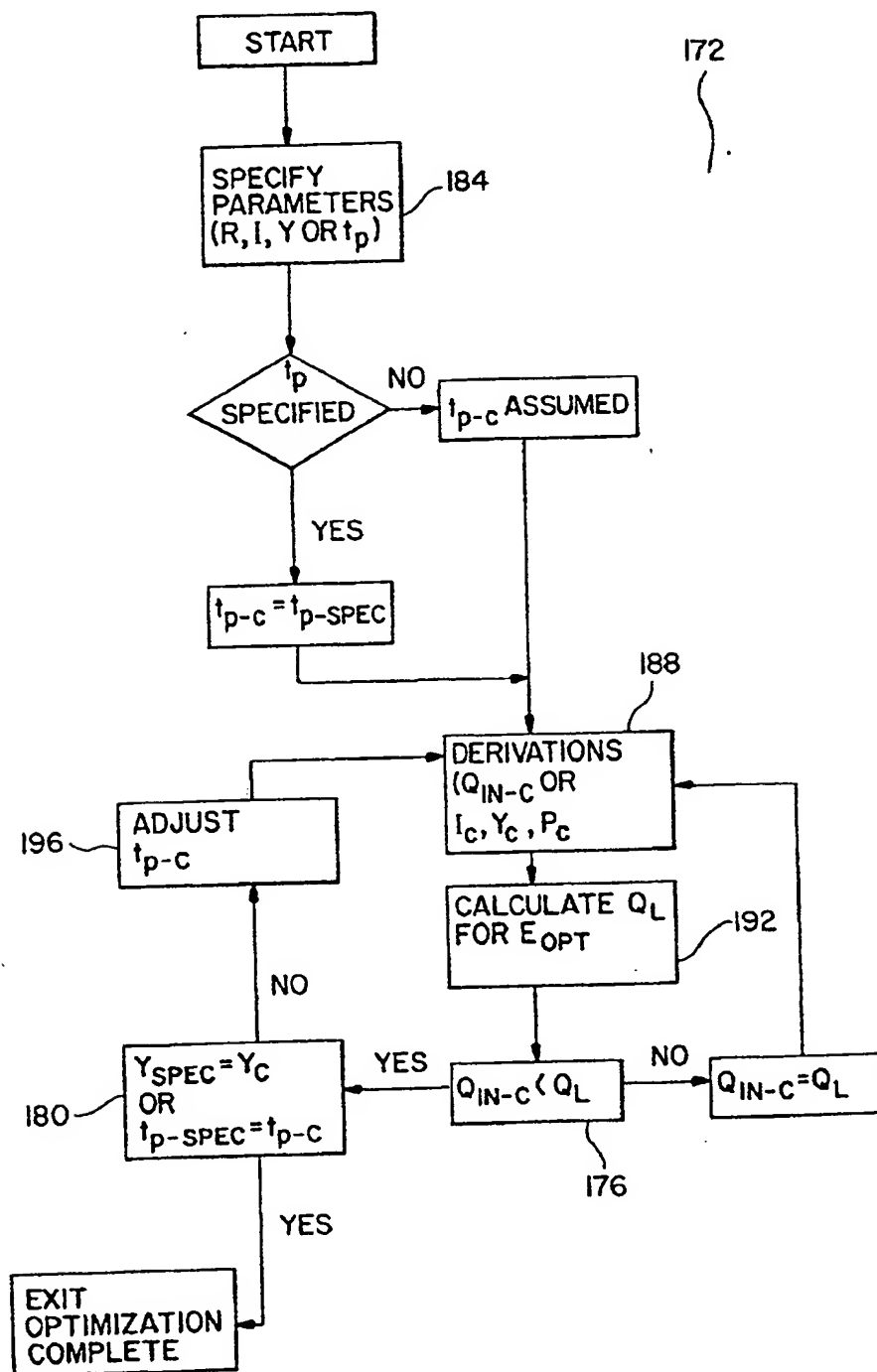


Figure 9C

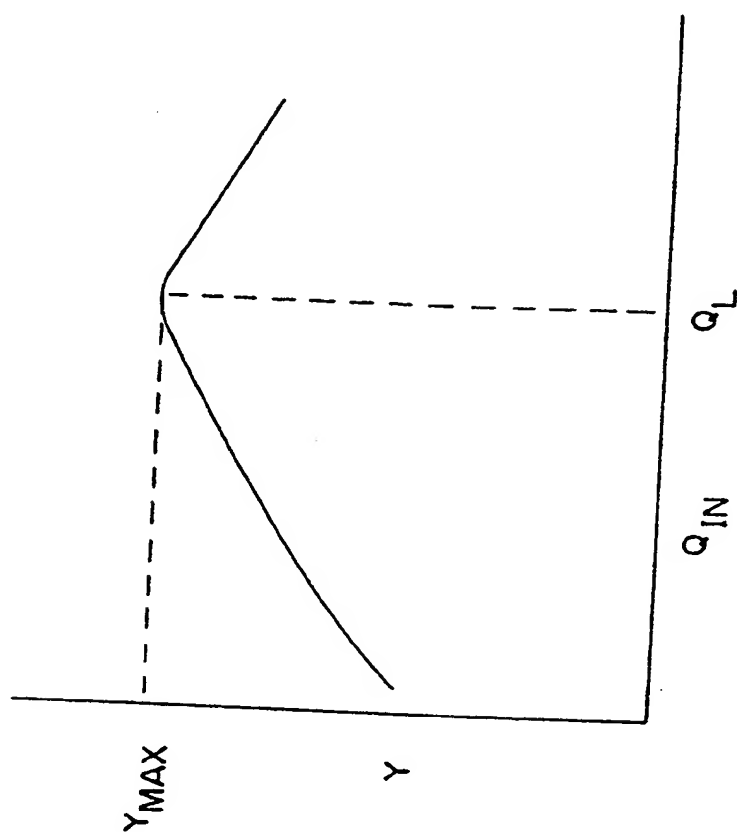


Figure 10

EXTRACORPOREAL BLOOD PROCESSING INFORMATION MANAGEMENT SYSTEM

[0001] This case claims the benefit of priority of U.S. provisional patent application serial No. 60/186,123, filed on Mar. 1, 2000.

FIELD OF THE INVENTION

[0002] The present invention generally relates to the field of extracorporeal blood processing systems and, more particularly, to providing information management and/or data manipulation and/or optimization capabilities to, in and/or with such systems.

BACKGROUND OF THE INVENTION

[0003] The utilization of blood taken from donors and transfused into recipients is well known for purposes of treating medical conditions. More recently, selected blood components have been separated and collected from donated blood for subsequent transfusion into recipients for the more specific therapeutic benefits of those particular blood components. The primary blood components of current interest in many separation and collection technologies include platelets, red blood cells, white blood cells, stem cells and plasma.

[0004] In the harvesting of blood components, blood is removed from a donor through a needle assembly or other blood access device and may thereafter be processed by centrifugation or other appropriate separation techniques to isolate and collect the desired components. This procedure is often carried out very effectively in an on-line procedure wherein blood is removed from a donor, processed in and through a disposable extracorporeal fluid circuit to obtain the desired components, and the uncollected components thereafter returned to the donor. Two illustrative blood component collection systems which provide for this type of on-line blood component collection procedure are the COBE® Spectram™ and Trima® apheresis systems which are commercially available from the assignee of the present application.

[0005] The yield of a particular collection of blood components from such a process is an important factor in the ultimate usefulness of those particular components. For instance, in the United States a minimum yield is associated with a collected blood component product in order for that product to meet certain criteria and qualify for use as a transfusable blood component product. The COBE® Spectra™ and Trima® apheresis systems presently accommodate for this requirement by processing certain donor biological data such as height, weight, gender, and platelet pre-count or hematocrit, together with pre-configured and/or operator-input data such as the total procedure time, and system-related data such as the type of collection procedure (e.g., single or double needle) and collection efficiency to generate certain process parameters such as the inlet flow to the apheresis centrifugation device (including, for example, the combined flow of whole blood from the donor plus typically a flow of anticoagulant). These apheresis machines then generate a predicted blood component yield from these data as well.

[0006] An additional consideration presently in the United States, for example, relating to blood component yield is that the yield is determinative of the product classification. With regard to platelets, a single platelet product is presently considered to be a collection of 3×10^{11} platelets and a double

platelet product is considered to be a collection of 6×10^{11} platelets. If a collection is between 3×10^{11} and 6×10^{11} platelets, it is still considered to be a single platelet product. This classification as a single or double platelet product is important to blood component collection facilities (e.g., blood banks/centers) since a double platelet product may have a higher selling price than a single platelet product and may also have a greater benefit for the recipient/patient. The yield of a particular collection of blood components may also be a relevant consideration for certain therapeutic treatments (e.g., red blood cell or plasma exchanges).

[0007] Furthermore, advances in blood component collection technologies offer the possibility of collecting multiple combinations of products from a single donor. These products can be defined within a large range of volumes and contents. Add to this multitude of collection choices, a multitude of donors with differing physiologies, each being subject to potential variations in collection procedures to yield a potential very large plurality of choices of products to be collected, as may be desired.

[0008] Still other important considerations relating to blood component collection systems relate to the donor and product demand. For instance, blood component collection facilities are not only experiencing an increase in the overall demand for blood components, but the demand now typically varies between the blood component types as well. Moreover, the supply of donors is unfortunately inadequate in many cases, and donor time constraints are becoming more prevalent. Furthermore, obtainable yields from a given donor may vary from one blood component to another, i.e., one donor may be a better platelet source than a red blood cell source.

[0009] The result is a large number of variables which must preferably be simultaneously managed in order to meet the blood bank collection goals which will thus also satisfy the needs of the ultimate hospital or like customer. Computerized information systems are tools which are beginning to prove useful in assisting in controlling parts of blood collection processes. This will likely further impact, if not transform, how blood banking will be managed in the future. Computer information systems may prove important in aiding the provision of just-in-time supply of products to meet customized demand for blood products and better satisfying the individual needs of patients and providers. Automated component collection systems will also allow for flexibility in producing customized blood products in a just-in-time fashion from potentially fewer donors to help meet the demands of patients and providers.

[0010] In view of the foregoing, it should be readily understood that better management of the various aspects of blood component collection processes and systems is increasingly desirable in providing preferred product collection and customer supply options.

SUMMARY OF THE INVENTION

[0011] The present invention relates in one application to a blood component collection system and the provision of management capabilities which may include the incorporation of data manipulation and/or optimization principles. Generally, the present invention preferably utilizes an information management system which provides simplified donor data storage and control as well as communications

with actual blood component collection machines to both ease and optimize the set-up and operation thereof. The principles of data manipulation and/or optimization are further improved also, particularly in terms of the individual donor, a given pool of donors, the particular blood component collection system, and/or the blood component product or products to be collected. For instance, the present invention may be adapted to provide for the collection of a predetermined quantity of at least one predetermined blood component, or more typically the collection of such blood components within a particular range in a "minimum" amount of time, and/or for the collection of a "maximum" quantity of at least one predetermined blood component in a fixed amount of time, all based upon certain donor and/or blood center defined process conditions. Moreover, the present invention may be adapted to provide for blood component inventory control by basing donor selection and/or collection procedure selection (in terms of the type of blood component to be collected) on blood component demand and/or existing inventory. In addition, the present invention may be adapted to provide for further donor management by collecting that blood component type or types from the donor which provides a maximum yield.

[0012] A preferred central computational, data storage, manipulation and communication system serving as the primary basis of the present invention is preferably a software-type of application run in tandem with one or more hardware devices including, for example, a data input device, a data storage device, a data manipulation device and one or more communications devices which connect in data communication relationship one or more of such input, storage and/or manipulation devices to at least one blood component separation and/or collection machine. The software application may be and in preferred form is operable in/on a Microsoft® Windows® software platform (or a similar such system) that allows blood donation center operators to prepare apheresis machines and donors for apheresis donations in an automated manner. The present system may preferably have two primary components, a computation/manipulation application with associated software and devices, and a server system also including associated software and devices. The computation/manipulation application is used by the blood center staff to perform data management and/or manipulation functions. The server system is used preferably to store data and provide communications with the apheresis machines and/or other information systems. In a typical setting, one or more operators from different locations within a single blood center and/or remotely from various disparate blood centers (and/or other sites) can communicate with a centralized server system to perform specific functions such as donor check-in, preparing a donor for a particular donation, or finalizing and/or preparing reports on collection activities, inter alia.

[0013] An important purpose of the present system is to address various challenges in the area of blood donation management including increasing productivity, better donor qualification/utilization and improved product quality control and disposition.

[0014] Increased productivity may be accomplished through centralized management of apheresis machine configurations. Operators and/or system administrators may easily create and store several configurations using the present system on a centralized server/computer or a like

environment. These configurations are preferably kept in a centralized database and can be downloaded to each apheresis machine on a permanent or a temporary/one-time donation basis. This reduces the inherent contemporary difficulty of editing apheresis machine configurations by allowing the operator to update a centralized configuration and not be required to repeatedly make the same change on several standalone apheresis machines.

[0015] Donor qualification/utilization may be improved through procedure customization and/or optimization. Each donation may be customized by this system to account for the current needs of a blood center and/or optimized by what each particular donor is eligible/qualified for or capable of donating. This allows the operator to determine what product or combination of products will best be collected even before the donor is connected to the machine. It also allows the blood center operators to see what tubing set is required for the donation. With this information the customer can avoid wasting tubing sets and reduce incomplete procedures. Decision support for donor eligibility is a preferred beneficial feature of the system. At a minimum, eligibility may be determined by the interval between donations, the number of donations previously given, the blood component loss over a period of time, and other donor screening issues.

[0016] Another important, yet optional feature of donor qualification/utilization and management in using a system of the present invention involves donor recruitment. The present invention provides a tool which may analyze and predict donation outcomes prior to running a donor on an apheresis machine. Such a tool can use donor and procedure information from the central database or optionally from an imported text file containing the required minimum information. Thus, such predictions can be used independently of actual runs on donors, even those actual runs involving the system of the present invention. These predictions may also be independent of procedures not currently entered into the central database, but rather from data generated by the blood center or data obtained from the blood center information system. Donor data may refer to a particular donor or to a statistical distribution of donor population. At a minimum, the system of the present invention may preferably analyze the outcomes of the following three scenarios: a) a single donor relative to many possible procedures; b) many donors relative to a single type of procedure; and c) many donors relative to many possible procedures.

[0017] Improved product disposition may be enhanced through the provision of alterable prioritizations of the product needs of a blood center. The present system presents the capability of providing a prioritization of which products are preferred to be collected. This allows the blood center to begin to incorporate the concept of demand drive where donors are used to fill existing and/or imminent product needs. This also reduces waste from the over collection of certain products. The system also presents the capability to tailor a blood center's priorities by blood type, CMV status, and/or HLA type matching.

[0018] The present system also provides for quality control (QC) in the entry of laboratory data for products collected by blood separation devices operated in accordance with the present invention. Data may include (but is not limited to) measured yields, volumes, concentrations, product contaminants, and pH levels. The present system

provides the capability to associate anomalous QC lab data to donation events and to generate exception reports where the device prediction and QC lab results may differ. The present system can also utilize this data to automatically calculate and adjust a separation device's yield calibration value, i.e., a yield scaling factor, depending on the particular device type.

[0019] Overall procedure and apheresis machine management may also be improved by recording procedure history information for each apheresis donation and storing it in a central database. Thus, the system may contain a detailed log of each donation. These logs can include procedure comments, tubing sets used, alarms experienced, adjustments made, and machine run summary information. Operators may additionally annotate this procedure history information and/or obtain reports using such logged information.

[0020] To implement the above and other features of the present invention, it is preferred that a central computational/data storage system be established according to the present invention so that it communicates with each of one or more blood collection machines, preferably apheresis machines, in both directions (even though one-way communications may be desirable in certain situations). Two way communications provide for directing to each machine configuration information of both temporary and permanent natures, procedural lists and priority information, donor vital information, including height, weight, gender, blood component pre-counts and total blood volume (TBV), as well as donor identification which may include a donor picture with the donor's name and perhaps the date of birth. The centralized system may then also communicate in the reverse direction with each machine to retrieve from each apheresis machine immediate information regarding conditions such as alarms, procedure adjustments, and run progress (product collection information) for monitoring purposes. It also provides for retrieving end of run summary information and run logs after each procedure is complete. The centralized system can also use data from the apheresis devices to detect and isolate potential maintenance problems before they manifest themselves to the blood center. These can then be reported so that preventive maintenance may be performed.

[0021] The present system preferably uses prediction algorithms like those used in the Trima® and/or Spectra™ apheresis machines. Moreover, the prediction algorithms can also be applied to individual donors, a reference donor list, and/or ranges of donors within the database. This capability is helpful to predetermine donor eligibility for specific product collections, and what products would be available given specific apheresis machine configuration settings.

[0022] The present system has been developed with an open architecture to provide integration capabilities and collaborative capabilities with other computing environments (such as Mak and/or Wyndgate donor database information systems) and/or with other component separation machines (such as the Haemonetics and/or the Baxter series, e.g., the MCS+ and/or the Amicus and/or CS-3000 apheresis machines, inter alia). This ultimately will allow ancillary applications to be used. For example, this allows for the manipulation and formatting of donor identification data and/or images obtained from other information or software systems. Bar code capability is another preferable alterna-

tive which may be incorporated into the present system. Any field entry point which could/would require keyboard data entry could be filled using a bar code reader. In addition, special entry fields such as unit or batch number, manufacturer and expiry dates of disposable tubing sets may be fully decoded utilizing administratively editable decoding information; an example is manufacturer identification of a disposable tubing set.

[0023] Products can also be customizable from a collection standpoint. This is a potential first step toward a "dosing" model whereby components may be collected in quantities matching specific medically or doctor prescribed doses. These customizable products, although perhaps not directly donor specific, could also be set up in a way to take care of situations such as a "first time" donor or persons known as "clumpers," i.e., those persons whose component products show a certain tendency to clump or aggregate.

[0024] After determining which product or products are to be collected, each donor can be assigned to a specific apheresis machine. Monitoring real-time machine status from a central system is useful to determine to which machine each donor should be sent.

[0025] The present system has been designed to satisfy an optional yet desirable three room operational flow scenario. The basic three room scenario involves processing donors sequentially through three steps which may correspond to three different rooms; namely, donor registration or reception, donor interview/screening and donor utilization rooms. This model has been suggested for providing smooth operation of the blood component collection process.

[0026] During or after the run, numerous standard reports may be made available to provide the donation center information related to specific runs, sequences of runs, exceptions, etc. Although the reports are preferably standardized, customization may also preferably be made possible through the simple use of report wizards. The present system preferably also utilizes an industry standard report engine.

[0027] The central database provides the system with the capability of storing and maintaining data relevant to the entire blood component collection process such as, donor demographic information, machine configuration information, run information and lab result information. Lab data can also be entered into the run record to complete the product collection run record. This data can be used to provide feedback to the process. The communication software and hardware enable the pulling of data from and transmission of data to a common or central data repository.

[0028] This system may be used in a stand-alone configuration or in collaboration with a blood banking information system, especially for transfer of donor demographics and like donor identification information. The blood center information system is preferably considered the master when linked. Fire wall protection may be provided through password protection schemes, message formatting requirements and/or hardware communications interfaces. This provides the assurance that the integrity of the apheresis machine is maintained during connectivity of this system with such machines(s) and/or with other systems. The present system can also utilize a "standard" customer network for communications between a central system server and operators.

This concept of collaborative networking particularly with pre-existing networks can minimize the "re-wiring" that otherwise might have been necessary.

[0029] Connectivity may also be utilized to provide collection data to the blood bank information system after the run is complete. This two-way communication strategy allows the present system to optimize the procedure and device selection based on the blood center's current priorities, rather than making these selections less-optimally at donor registration time. The as-run collection data may also synchronize the blood bank information system to the actual products, yields, and volumes donated.

[0030] Further, this system preferably utilizes formal and de-facto standards such as SQL interfaces to the database, ethernet protocols for communications, and preferably Oracle® reports for report generation.

[0031] In the present system, an apheresis machine, which is preferably also operable in an off-line mode, may upload run information to a central server system when the apheresis machine is connected on-line with the central server system. This feature could also be used for mobile or satellite operations.

[0032] An additional preferred functionality is connectivity with a blood center information system. Donor data will preferably be down-loadable to the central server system of the present invention from the blood center information system. This will allow real time updating of donor data in the central database of the present invention from the database of the blood center information system. Other alternatives of the present system may also include connectivity of the central data manipulation and/or storage system to apheresis machines from a plurality of manufacturers.

[0033] Of the various methods of data transfer available, an option is a web server set-up. With specially developed applets, this allows the local user or a remote user (with permission) to browse the operator's database for pertinent information. Thus, this system can also be accessed remotely and provides an external "gateway" to run-logs from each apheresis machine. Security can be established to obscure sensitive data. An administration/security optional feature would allow the system to be configured with the concept of user types for security. A system administrator would have the most privileges and a guest would have the least number of privileges.

[0034] The present system provides an opportunity to circumvent shortcomings in the operational procedures forced on a blood center by the use of pre-existing blood bank software. Specifically, the present system may overcome the problem of a blood bank software system pre-selecting blood components to be collected rather than having the present system perform this selection process. The way this is achieved is unique in that data is exchanged with the blood bank software system during the process flow of information. This is different from having either system depend on inputs from the other system and then wait for outputs.

[0035] The present invention also preferably may be characterized as a blood component collection system having blood component product-based or time-based optimization capabilities. One embodiment comprises a method for collecting at least one predetermined blood component (e.g., a

collection of platelets or red blood cells or plasma) from a source of whole blood using a blood component collection system which includes a blood component collection device running according to a particular collection procedure. More particularly, a desired yield of the predetermined blood component(s) may be identified (such yield including a single yield or range of yields) and biological data relating to the source of whole blood is provided to the blood component collection system. This data may also include statistically developed modifications based upon categories of data for multiple sources of whole blood as contained within the central server systems. Also, a value or magnitude may be associated with each of the various process parameters used in the collection procedure. A magnitude of at least one of these process parameters is preferably derived from the biological data and the desired yield and optionally also the statistically derived data from a plurality of whole blood sources. These magnitudes, including all magnitudes of process parameters derived from the desired yield, are input to the blood component collection system. Thereafter, the collection procedure is performed with the blood component collection device and with the input process parameters to collect the desired yield of at least one predetermined blood component(s) from the whole blood source.

[0036] In a time-based optimization method, a total procedure time for the collection procedure is identified (e.g., based primarily upon donor time availability). One potential inlet flow to the system is derived from at least this identified total procedure time. Another potential inlet flow to the system is derived which provides an "optimum" collection efficiency and is effectively the apex of a bell-shaped yield/inlet flow curve (i.e., the inlet flow which provides the maximum blood component yield). Consequently, if the total procedure time-based inlet flow is greater than the maximum yield-based inlet flow, and thus is an inlet flow on the decreasing slope portion of the yield/inlet flow curve, the maximum yield-based inlet flow magnitude is used in the performance of the collection procedure. However, if the total procedure time-based inlet flow is less than the maximum yield-based inlet flow, and thus is an inlet flow on the increasing slope portion of the yield/inlet flow curve, the total procedure time-based inlet flow magnitude is used in the performance of the collection procedure.

[0037] The subject invention provides greater efficiency in blood component collection and management. For example, the present invention can be used to compare blood bank/center component inventories with projected needs, and adjust collection procedures to meet these needs. Further, the present invention provides benefits to donors. In particular, certain information relating to the donor's physical and medical characteristics may be stored in the system and utilized during subsequent visits by the donor to derive magnitudes for the various process control parameters. For example, for a donor with an anticoagulant intolerance, the magnitude of the anticoagulant infusion rate may be set so as to not exceed the donor's tolerance.

[0038] The present invention may be implemented as a computer process, a computing system or as an article of manufacture such as a computer program product. The computer program product may include a computer storage medium communicatively connected to and/or readable by a computer system and may include encoding of a computer program of instructions for executing a computer process.

Such a computer program product may also be a propagated signal on a carrier readable by a computing system and may also include encoding of a computer program of instructions for executing a computer process.

[0039] These and other features of the present invention can be better understood from the following detailed description of a preferred embodiment of the present invention taken in conjunction with the accompanying drawings which are briefly described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0040] FIG. 1A is a schematic representation of a blood processing information management system in accordance with principles of the present invention;

[0041] FIG. 1B is another schematic representation of a blood processing information management system in accordance with principles of the present invention;

[0042] FIG. 1C is yet another schematic representation of a blood processing information management system in accordance with principles of the present invention;

[0043] FIG. 1D is still another schematic representation of a blood processing information management system in accordance with principles of the present invention;

[0044] FIGS. 2A-2I are display screen depictions of data entry, retrieval and/or manipulation display pages for use in accordance with the present invention;

[0045] FIGS. 3A-3F are further display screen depictions of data entry, retrieval and/or manipulation display pages for use in accordance with the present invention;

[0046] FIGS. 4A and 4B are still further display screen depictions of data entry, retrieval and/or manipulation display pages for use in accordance with the present invention;

[0047] FIGS. 5A and 5B are yet still further display screen depictions of data entry, retrieval and/or manipulation display pages for use in accordance with the present invention;

[0048] FIGS. 6A through 6M are another set of display screen depictions of data entry, retrieval and/or manipulation display pages for use in accordance with the present invention;

[0049] FIG. 7A is a schematic representation of one embodiment of a blood component separation assembly which utilizes a dual needle configuration and which may be incorporated into the blood component collection systems of FIGS. 1A-1D;

[0050] FIG. 7B is a schematic representation of one embodiment of a blood component separation assembly which utilizes a single needle configuration and which may be incorporated into the blood component collection systems of FIGS. 1A-1D;

[0051] FIGS. 8A and 8B are isometric and top views, respectively, of one type of a disposable blood processing channel which may be used in the blood component collection device of FIGS. 7A and 7B;

[0052] FIG. 9A is a flow chart of a blood component collection procedure utilizing principles of the present invention;

[0053] FIG. 9B is a flow chart of one optimization model for deriving at least one optimal process parameter from a desired blood component yield or from a total procedure time in accordance with principles of the present invention;

[0054] FIG. 9C is a flow chart of one optimization model for deriving at least one optimal process parameter from a desired blood component yield or from a total procedure time in accordance with principles of the present invention; and

[0055] FIG. 10 is a yield/inlet flow curve.

DETAILED DESCRIPTION

[0056] The present invention will be described with reference to the accompanying drawings which assist in illustrating various pertinent features hereof. One application of the present invention involves one or more blood component collection systems which separate, remove, and collect at least one type of blood component (e.g., platelets, red blood cells, stem cells, white blood cells, plasma) from a source of whole blood (e.g., a donor) through utilization of a collection procedure derived from a typically site-configured and/or operator-input goal or set of goals and may optionally also include a "maximization" of at least one process control parameter. This type of maximized parameter derivation is referred to herein as an "optimization process" and the derived process control parameters may be referred to herein as "optimal values."

[0057] Referring to the schematic of FIG. 1A, a first alternative schematic representation of the present invention is shown as including a blood component collection and information management system generally identified by the reference numeral 2. The system 2 would typically be implemented at a blood bank/center (not shown in FIG. 1A). The system 2 may include a substantially centralized computing/data storage assembly 140 (e.g., including an appropriate microcomputer and/or microprocessor(s) such as a Windows®-based standard desktop or laptop computer (or other like platform(s)), including therein or communicating with at least one memory device with corresponding appropriate software, etc. (not shown separately in FIG. 1A)) and at least one blood component separation/collection assembly (three shown), each generally identified with respective reference numerals 10 (in FIGS. 1A-1D). Each such separation collection assembly 10 preferably includes a blood component separation and collection device 18 as an integral part thereof. As will be discussed below, the centralized computing/data storage assembly 140 (or at least a portion thereof) and the associated blood component collection assemblies 10 are preferably appropriately interfaced with each other in electronic or electromagnetic data communication relationship as will be described, but may also and/or alternatively be disposed in a physically separate disposition from each other particularly during non-communication operation. That is, component separation/collection, data communication, retrieval, manipulation, and optimization procedures in accordance with principles of the present invention are not limited to being performed at any particular physical location of apheresis machines(s) 10 relative to a central assembly 140. Furthermore, data entry, manipula-

tion and storage may still be performed at/on each machine 10 using, for example, respective interfaces, which here are shown as preferred touchscreen input/output devices 199.

[0058] A further aspect of the present invention is shown in more detail in FIG. 1B wherein a centralized computing/data storage assembly 140 is shown schematically disposed in communicative relationship with various types of blood component collection machine assemblies 10 as well as to either a discrete blood center information system within a blood center 1000 or a hospital information system within a hospital 1001, or both. Thus, as will be described in further detail below, a centralized computing/data storage assembly 140 may preferably make broad use of multiple communication connections (including satellite and/or wide area networks (WAN's), for example). Note also that though preferable connections to Trima® apheresis machines 10 (available from the assignee of the present invention) are shown and described throughout; these are intended as exemplars only. As shown in FIG. 1B, connections can be made to numerous other machines as well, such as COBE® Spectra™ apheresis machines and/or Baxter, Inc. and Haemonetics Corporation apheresis machines (such as the CS-3000, the Amicus and the MCS+ apheresis machines, inter alia). The currently preferred machines 10 are, as shown, Trima® apheresis machines 10 (see e.g. FIGS. 1A-1D). However, a representation of a COBE® Spectra™ machine is also shown in FIG. 1B, identified therein generally by the reference numeral 10A, and a Baxter Amicus machine and a Haemonetics MCS+ machine are also shown in FIG. 1B and identified by the respective reference numerals 10B and 10C. Use with a more traditional manual whole blood collection system is also shown schematically in FIG. 1B, generally identified by the reference numeral 10D, therein. Thus, this system is intended to and will operate with various apheresis as well as whole blood collection systems.

[0059] Generally, a centralized computing/data storage assembly 140 may include, as shown schematically in FIG. 1A, a central station 148 which may include, for example, data input/entry devices generally identified by the reference numeral 149. Such devices 149 may, more particularly, include a keyboard 149A, a mouse 149B, and/or if desired, devices such as a barcode reader (not shown), and/or a digital camera (not shown) and/or an input/output display monitor and screen 200 as these may be known in the art. Various internal hardware and software elements, again as known in the art are also intended to be included within a central station 148. Further, the centralized computing/data storage assembly 148 may include a data manipulation device 144 (disposed within station 148 in FIG. 1A) which is preferably closely associated with and in some embodiments is perhaps inseparable from the central station 148. Manipulation device 144 may be an appropriate processor as used in a computer system such as may be used in a microcomputer or otherwise standard desktop or laptop personal computer (PC) including a preferably Windows®-based operating system and may further include other devices and attendant manipulation software (whether resident on/in the processor or resident in other associated memory devices but closely associated with the processor). A further preferred element of the computing/data storage assembly 140 is the storage medium 142 (not separately shown from central station 148 in FIG. 1A) used for data storage. The storage medium 142 may also be closely

associated with the other elements of the assembly 140, i.e., the central station 148 and the manipulation device 144, or as with those other devices it may be dissociated in physical space but communicatively associated therewith through space (via cabling or energy wave communications, inter alia), so long as these elements cooperatively interact functionally. Hardware and software which may make possible data communication between various elements of assembly 140, as well as between assembly 140 and myriad possible external devices, some of which are like those shown in FIGS. 1A and 1B, are hereafter referred to as a communication or server subsystem 146. Subsystem 146 may also be mainly disposed on or in the assembly 140 and/or may be mostly physically disparate therefrom so long as it provides the data communication functions described herein.

[0060] Thus, the assembly 140 may be referred to as a whole for performance of the inputting and maintaining of donor-related data functions (principally through use of the central station 148, communication subsystem 146, and the storage medium 142), and also typically for the preparation of an initial procedure order (the process control parameters derived from the donor-related data and other considerations) for a given donor (through use primarily of the data manipulation device 144 together with the data obtained from either or both of the other elements 148, 142 as communicated by and through the subsystem 146).

[0061] Though perhaps not preferred, there may remain various situations in which it may be desirable to maintain the ability to perform data entry and/or manipulation procedures/ functions at the corresponding pre-existing operator interface 199 of each particular apheresis machine assembly 10 as well. In such situations, a central computing/database assembly 140 may thus not be required for operation of assembly 10 even if still provided. Note in the preferred apheresis machines 10 shown in FIG. 1A (such as the Trima® machines 10 described above), the computing/database and data entry and manipulation capabilities are available in and would thus be able to continue to separately provide these functions, if desired. Moreover, this could still occur even when connected through a central communications system 146 to a central assembly 140 such that the computer/database assembly 140 may still collect/retrieve data from the one or more apheresis assemblies 10 even if the central assembly 140 is not used to program the respective machines 10. However, where a central computing/database assembly 140 is employed as preferred herein, this donor-related data and/or initial procedure order is preferably generated by the central computer/database assembly 140 and then transferred to one of the apheresis machines 10 (via an RS/232 or other similar interface, among other communications options such as energy wave communications, inter alia (see further descriptions below)). In either event, the operator is preferably provided with one or more data manipulation or optimization options, whether through the central data manipulation device 144 of a centralized computing/data storage assembly 140 or the data manipulation capabilities of the apheresis machines 10 themselves. Note the data manipulation and/or optimization options provided by a central assembly 140 may provide a different set of process control parameters than an initial procedure order that might result from data entered manually on the apheresis machine 10 because the data manipulation and/or optimization on a central assembly 140 may be based upon one or more previously specified and central database stored

conditions/goals (e.g., input blood component yield, input procedure time) and one or more particular derivations for the process control parameters. Generally, more flexible options would be available from a central server system 140 than those previously available on discrete machines 10. Moreover, if an optimization option is selected at the central server 140, a manually-entered procedure order may be modified to reflect the results of such an optimization and the collection procedure may be initialized/reinitialized with the results of the optimization (i.e., the collection procedure could be reinitialized in the less preferred case of an optimization which is performed after the collection procedure has been started and such a case is referred to as a downstream optimization). The collection procedure may then thereafter be performed by the respective blood component collection device 10.

[0062] The concept of optimization here generally refers to achieving the maximum or best product output depending upon certain circumstances (e.g., obtaining the most product in a certain specified time or achieving a specific yield in the fastest time). On the other hand, the concept of data manipulation is more generally here intended to have a similar yet less exacting connotation, such that perhaps the best or maximum output may, but will not necessarily be the result. Thus, data manipulation is here intended to encompass optimization calculations in addition to providing perhaps less than optimum but still high efficiency results depending on certain further combinations of criteria. Thus, data manipulation is intended to generate more and/or perhaps better options to the blood donation center. For example, blood centers may prefer or determine to require certain combinations of products from certain blood type donors 14 (see FIG. 1B); then the blood center 1000 can prioritize this in the computer/database 140 so that those donors will donate those combinations even if the particular yields or donation times are not fully optimized according to the concept of optimization set forth above. Thus, yield or time optimization can be made secondary to other data requirements and/or manipulations. Note also that optimization and/or manipulation may be performed without requiring the central system 140 to collect/retrieve data from the various apheresis assemblies 10. Thus, communications may be made only one-way to (or from) the apheresis assemblies 10. Further, a preferred purpose for performing the optimization and/or manipulation functions centrally is to allow selection of the donation procedure prior to connection of a donor to a machine 10; thus, a particular product or products and the corresponding tubing set (if there are distinctive such sets) may be selected prior to machine set-up and donor connection. Also it could prove that the donor may not be able to provide a useful donation (for the end recipient/patient 15; see FIG. 1B), and this could thus be determined prior to machine set-up and/or donor connection.

[0063] Nevertheless, before describing the preferred manipulation/optimization processes of the present invention in any further detail (see description relative to FIGS. 7-10, below), two further, non-exhaustive alternative system embodiments will first be described. Referring first to FIG. 1C, an alternative centralized computing, communication and data storage assembly 140A is shown. Assembly 140A includes a central station, here referred to as a central data server 148A, which may be substantially like the central server 148 in FIG. 1A, at least preferably in primary function. At least a storage medium/database 142A and

preferably also a data manipulation device 144A, each again substantially like those described relative to the embodiment of FIG. 1A are also preferably disposed within the central server 148A of FIG. 1C. However, in the embodiment of FIG. 1C, the communication sub-system identified generally by the respective reference numerals 146A and 146B, is shown as preferred here discrete therefrom, in two general sub-parts, referred to respectively as the machine network 146A and the client network 146B.

[0064] Machine network 146A preferably includes a network terminal server 1210 with a connection 1212 between the server 148A and the terminal server 1210. Respective connections 1215 are also shown as disposed between terminal server 1210 and each of the separation/collection machines 10. Connections 1212 and 1215 may typically be RS/232 cable-type connections, or other alternative data communication connections may be used including such options as radio, microwave or other electromagnetic wave communication systems (not specifically shown). Note that other separation/collection machines/systems, such as systems 10A, 10B, 10C and 10D (from FIG. 1B) may also be connected to/through the illustrated terminal server 1210 or a further discrete server (not shown).

[0065] A similar, though preferably discrete, network terminal server 1220 is also shown in FIG. 1C to illustrate a preferred communication sub-system for the client network 146B. A connection 1222 between the central server 148A and the terminal server 1220 is also shown, as are respective connections 1225 from the terminal server 1220 to one or more data input/output/manipulation stations 149C (two shown here). Connections 1222 and 1225 may here also typically be RS/232 cable-type connections, or take other data communication forms including, for example, energy wave communication forms. Note also that other devices (not shown) might also be connected or connectable to/through the illustrated server 1220, as for example, one or more printers (not shown) or other accessory devices. Note, stations 149C may contain, as above, one or more various input/output devices such as keyboards, mice and/or screens (as shown) or otherwise (barcode readers, digital cameras, etc., not shown). Moreover, as decentralized stations, these assemblies may also generally include computing devices and/or capabilities such as may be included in standard desktop or laptop computers, including the stations 148B as shown, and potentially data storage/memory and/or data manipulation devices and/or software along with potential resident communications devices and/or software.

[0066] Separating the machine network server 146A from the terminal network server 146B allows for isolating and/or protecting communications therebetween, as may be desired. Thus, the respective servers may have on one side, a network connection to the central server 148A using discrete I/P (Internet Protocol) address information, and on the other side, RS/232-type connections to the respective end devices (machines 10, and/or input/output devices 149C, e.g.). In this fashion then, each network may be kept private from each other such that the I/P's are essentially hidden from each other by the central server 148A. A firewall communication protection setup as known in the art may thus be established.

[0067] A further alternative communication sub-system 146C is shown in FIG. 1D. Sub-system 146C generally includes a network terminal server 1230 with respective connections 1232 which connect respective central servers 148C to network terminal server 1230. RS/232 or other

communication connections (as above) may be used here as well. In this way, two or more centralized servers 148C may communicate data with each other. Thus, central servers in two or more physically separate clinics may communicate with each other. Such a system may also be used for communication with other information systems (blood center information systems or hospital information systems) such as is schematically shown in FIG. 1B. Other similar communications can also be made in this way, as for example to help or maintenance centers (not shown), as described below. Firewall types of communication protections may also be set up here, such as was described above. Thus, network connections can be made between each central server 148C and the network terminal server 1230; whereas RS/232-type communications can be established elsewhere. Note, all variations of system 140 may include communications connection(s) of many different sorts which allow each particular device to communicate with other devices. RS/232 communications connection(s) as described, are only examples of such communication media. Communication media may typically embody, be embodied in or otherwise be capable of interacting with and/or through computer readable instructions, data structures, program modules or other data in a modulated data signal such as a carrier wave or other transport mechanism and include any information delivery media. The term modulated data signal may include a signal that has one or more of its characteristics set or changed in such a manner as to encode information in the signal. By way of example, and not limitation, communication media may include wired media such as a wired network or direct-wired connection, and wireless media such as acoustic, RF, infrared and other wireless media. The term computer readable media as used herein preferably includes both storage media and communication media.

[0068] A more detailed description of the preferred steps for using the present preferred system will now be set forth. In FIGS. 2A-2I, inter alia; use of the centralized computing/data retrieval assembly is shown in more detail. First, FIG. 2A depicts an exemplary display page or screen 201 which may be the first such screen displayed on the output monitor display screen 200 (see, e.g. FIG. 1A) of the centralized computing/data storage assembly or system 140 when the software thereof is initially accessed. A more, rather blank, screen (not shown) may be used as an initial screen upon startup, as described below. As can be seen in display screen 201 generally, the initial donor information may be gathered here, such as for example the donor's name (last and/or first), and/or the donor's identification (ID) number or like identifier (if used), and/or the donor's telephone number or other identification data (also if used, not shown). Data entry fields for these types of data may be seen in the main work area 202. These are several examples of possible initial identifiers among numerous others which could be alternatively substituted herein.

[0069] Moreover, as mentioned this could be the first display screen to be shown upon software initialization, or other alternatives (not shown) could be simply used preliminarily hereto by way of introduction to this or a like display 201. In any event, some display is preferably used as the starting point for data entry (and/or search, if the data were previously entered or imported from another system) for use with a particular donor, and for the sake of convention, display 201 will be used in this role for this description

of the preferred embodiment. Note also, that as shown in FIG. 2A, disposed next to the main work area 202 (with sub-areas 203 and 204 as will be described below) is a procedure icon selection area 205 which is depicted along a vertical portion of the left-hand side of display 201. In it, five icons 207, 208, 209, 210, and 211 are currently shown, though either more or fewer such icons could be used as may be desired.

[0070] A description of the preferred general overall procedural flow will be set forth starting with particular reference to the procedure icon bar 205 on the left side of the display screen 201.

[0071] As an initial step or sub-procedure, the Select Donor icon 207 represents the performance of several functions generally described as follows. First is a Greet Donor function wherein the system operator may verify and/or add a new donor record to the system database 142, and check-in a donor into the system 140 (either by data entry directly into this application or via automatic transfer of data from a discrete blood bank information system). Thus, the operator may perform Donor Entry/Edit functions to enter or modify a donor record in the database (see e.g., FIGS. 2B-2I, as described below). This may also include capturing a donor image using a digital camera to take the donor's photo (this functionality may also or alternatively be part of the Prepare Procedure Wizard process; see below). And, this may include use of a barcode reader to enter barcoded data such as the donor ID, etc. (Note: this data input functionality may also be part of other processes in this system such as the Prepare Procedure Wizard (entering barcoded unit number) and/or the Finalize Procedure Record (entering barcoded lot number/data for supplies).)

[0072] After the data entry/verification, the next general step would preferably be to Prepare the Procedure for component collection as indicated by the second icon 208 in bar 205 as shown in FIGS. 2A and 3A, inter alia. This preferably involves using a Prepare Procedure sub-procedure or software wizard to record further donor information and select the procedure to be run on the donor prepared as set forth above (see description relative to FIGS. 3A-3F, below).

[0073] Next, the operator preferably uses the Assign Machine icon 209 to access the sub-procedure for assigning the donor to a particular apheresis collection system 10. More details of this process are described below with particular respect to FIGS. 4A and 4B.

[0074] As shown generally in FIG. 5A, the central system 140 may be used for monitoring the procedure/machine status after the assignment of a donor to a particular machine. An icon 210 (FIGS. 2A and 5A) is preferably included for accessing this functionality in the left-hand procedure icon area 205. Screen 501 (FIG. 5A) reflects the first step in such a monitoring sub-procedure. Finalization of the Procedure Record may also be performed here, wherein the operator may enter procedure data, including operator roles and supplies entries. (Note: this record finalization functionality may also be part of the Select Procedure process below.)

[0075] Another optional step in the overall procedure shown in FIGS. 2A and 6A by the icon 211 is the Select Procedure sub-procedure where the operator may search for

and select a procedure (either active, pending, or finalized). A screen 601 such as shown in FIG. 6A may then be displayed (as described in further detail below). The operator will then be able to enter lab results by entering procedure product volume/quality information returned from the lab. The operator may finally prepare a Report on the Procedure by generating procedure or donor or production reports.

[0076] It ought to be noted that the various sub-procedures identified by the respective icons 207-211 can be selected at any time in the overall procedure to view, input or modify particular desired information. As an example, but not to be considered in any way as a limitation, the assign machine icon 209 could be selected at anytime to view the list of available and/or assigned machines 10. However, it should be noted that certain functionalities may thus be unavailable if an icon 207-211 is selected without having completed a previous sub-procedure. For example, upon selection of the assign machine icon 209 as suggested here, the assignment function will not be available unless at least one donor has been processed through the Prepare Procedure sub-procedure (see description, below). In such a case, where no donor has yet been so processed, there would not appear any donor icon in the donor assignment queue of screen 401 (FIG. 4A), even if the available and assigned machines 10 may be shown in the machine list. Similar functionalities preferably requiring pre-completed sub-procedures (thus building on previous module completion(s)) are identified throughout the below descriptions.

[0077] Although not a part of the general run procedure (and thus not involving or resulting from the clicking of icons in the procedure icon area 205), Administration Tasks (extra security being preferably required to access these options) may generally include: Setting Up the Application including setting default values; setting the apheresis machine configuration(s) including creating and/or modifying apheresis collection system configurations; Defining Products including establishing an unlimited number of product definitions; Defining Procedures including establishing an unlimited number of procedure definitions (combinations of product definitions); Defining Focus Lists including establishing an unlimited number of procedure focus lists (prioritization of procedure definitions); Performing Database Administration including managing and maintaining the data stored within the central database; and Blood Product Prediction wherein a blood product forecast-report may be generated.

[0078] Returning now to FIG. 2A, a more detailed description of the preferred overall procedure will now be set forth. In an initial start-up mode of software initialization, the main work area 202 could be adapted to display a preliminary display screen (not shown) which has no active work spaces. Then, after log-in (see below), the operator could be forced to select an icon from a menu list and/or from the left-hand procedure icon selection area or bar 205 in order to initialize the overall procedure. As an example, the operator could first select the select donor icon 207 with a computer screen cursor or pointer (not shown) and click the enter or mouse button (neither shown) as is known in the art of standard desktop or laptop computer, Windows®-based or like software applications. This selection could then bring up the shown display 201 for beginning a donor check-in procedure. A few further alternatives for use in

start-up (as well as throughout operation) may be found in the toolbars located as shown horizontally along the upper portion of the display 201. These are toolbars much like those used in a plurality of computer Windows®-type software applications with numerous functional similarities and specific distinctions as described herein. For example, the software start-up to the initial working display may also be achieved by selecting the "Tasks" menu heading 216 in the top level menu toolbar 215 and then selecting the appropriate "open" file command (not shown) or other like commands as are generally known in the art. Or, similarly, a small icon toolbar 217 may be configured to be used for initiating software procedures, as may also be generally known in the art. Other menu headings and/or icons (not shown) in toolbars 215 and/or 217 (or otherwise, not shown) may be used for other functions in startup or otherwise.

[0079] A third toolbar 220 may further be used in or even prior to software initialization or it may not be opened until the main work area 202 has been opened. The third toolbar 220 as shown and preferred herein has a location for the typing of a name or other identifier which may be used to begin the process of either data entry for new records or a search for existing records. This third toolbar 220 is preferably used for identifying the operator of the system, such identification being useful for logging-in and/or assessing the operator's level of security clearance, inter alia (described below). Thus, it is preferred that this operation of logging-in the operator be completed first. Further, it is preferred that a system administrator have previously established authorized users, with log-in names and optional passwords. The log-in names may then be typed in the blank space in tool bar 220, or the down arrow may be selected and clicked to reveal the list of authorized users to be selected. Once a user log-in name is entered, then a pop-up dialog box/window (not shown) may be made to appear to prompt entry of an appropriate password. Note, password and/or user log-in names may be made editable via such a pop-up dialog box/window (not shown) or may be restricted to editing by a system administrator. Further similar options may also be used for these initialization procedures as may be known in Windows® or Windows®-like environments.

[0080] Returning now to the main work area 202 of the display screen 201, two sub-areas 203 and 204 are shown in which data may be entered or displayed. First, as shown in sub-area 203, data concerning the identity of the donor to be checked-in may be entered in order to begin the donation process. The computer/database system 140 may then be made to search its database 142 (by selection of the search button 218 by the operator) to determine whether this particular donor has been previously entered in the system. If so, the system 140 returns the results of that search in the search results sub-area 204. Note that the search may be made dependent on any of the criteria set forth in the first sub-area 203 (or others not shown herein but alternatively usable herewith). Also, the search mechanism may be adapted to search wild cards and/or truncated terms or list various short forms for further search as these and other search capabilities are known in the art. As such, when typed into the proper field, this display screen simply calls up a donor from the existing database if such a donor exists therein. A search/query format may be used wherein typing an alphabetical initial will call up into the results window 204 all donor names beginning with that initial. The operator may then double click on a listed name to select and call up

the next preferred screen (see FIG. 2B, the donor entry/edit screen 221), which contains greater detailed donor information as will be described below.

[0081] First, however, several other graphical buttons are shown in the main work area 202 of FIG. 2A and may be used to perform various functions. For example, below the work sub-area 204 are examples of three buttons which could be set forth on this or any other alternative display screen used herein. In this example, the three buttons here are the "new" button 212, the "select" button 213 and the "help" button 214. The "new" button 212 could be used to toggle to a fresh search page like this one 201 shown without any information in any of the fields (name, ID, or results). Alternatively, the "new" button 212 could allow for either new data entry editing directly in the fields shown here in screen 201, or could be used to call up a secondary display screen, such as the Donor Entry/Edit screen 221 shown in FIG. 2B (described below). Such a "new" screen would preferably have empty fields to allow for new donor information data entry. Note, the "new" button 212 is shown in active, darkened mode in FIG. 2A as compared to the other "grayed-out" buttons 213 and 214. This means it is active as shown (and as would be understood to those knowledgeable in the art of common, conventional Windows® and the like software applications). It is active as shown when it may be desirable to enter new data records into the system. The "grayed-out" "select" button 213, on the other hand, is inactive until a search result record is displayed in sub-area 204. When such a record is made available, button 213 would be made active and darken in style such as the other active buttons shown here. The "select" button 213 provides for the selection of a donor data record to be verified and/or modified for preparation of a collection procedure. This functionality as well as that of the "help" button 214 is described in greater detail below.

[0082] As next shown by the donor data entry/edit screen 221 in FIG. 2B, data can be either manually input into the computer/database system 140 by typing into the corresponding fields such as will be described further below. Or, any appropriate data input can be performed with an alternative input system such as, for example, a bar code reader (not shown), or input from other computerized information systems as will be described below and/or become obvious to those skilled in the art. If using a bar code reader, a donor may be given a donor identification (ID) card which may have a bar code imprinted thereon which represents that particular donor's data. Then, an optical reader (not shown) can be used by the operator to read the bar code information from the card to fill in the donor data fields shown in FIGS. 2B-2I. The other previously introduced alternative input process would be in taking advantage of other pre-existing database/information systems which may already contain the appropriate donor data. Thus, the present computer/database system 140 may be disposed in data communication relationship with one or more such pre-existing systems and simply upload the desired data therefrom. Thus, the fields such as those shown in FIG. 2B, et al., can be automatically populated from the blood center's management information system (e.g., Wyndgate, MAK, etc.). In this situation, the reception portion of the data entry process (i.e., initial data entry and/or verification) could take place entirely on the blood center receptionist's computer in the corresponding Wyndgate or MAK (or like) system. This information may then be retrieved by and/or forwarded to

the computer/database system 140 to populate the fields such as those shown in the display 221 of FIG. 2B. This display 221 may be referred to hereafter as the Donor Entry/Edit screen 221 and may, in the three-room model, initially be called up in the what may be referred to as the "Reception" room. This three room model will now be briefly described.

[0083] There may be considered three main data input/verification points in a collection process. At the first point, hereafter referred to as "Reception," the donor is checked into the overall process. Under a scenario of data connectivity between the central computing/database system 140 and a blood bank information system, the "Reception" room/step may be handled through the blood bank information system and the needed donor data may then be automatically transmitted (downloaded or uploaded or otherwise) into the central system 140 as described above. With this connectivity between the blood center information system and the central system 140, the historical donor data (which may be batch file loaded into the central system 140 periodically) may also be called up and the donor may then be assigned to the second room, hereinafter also called the "Screening Room." In the screening room the donor information may be retrieved and displayed and several preferable pieces of lab data may be input for purposes of selecting the proper/preferred collection procedure to be performed. A donation unit number may also be assigned at this point. The central system 140 may, but preferably does not, hold confidential donor information influencing potential deferral; this information would preferably reside only in the blood bank information system. The central system 140 is preferably only concerned with the collection process. In either the "screening room" or the third room, hereinafter also called the "Donation Room," the donor may be assigned to a particular apheresis machine. The procedures performed in the donation room may also include recording other data about the procedure such as recording the identification numbers associated with the disposable tubing set. Once the donor is assigned to a machine, the central system 140 would preferably go into a monitor-only mode relative to that donor and that machine for monitoring and/or recording any and/or all events in the procedure. More details hereon are provided below.

[0084] Returning to the donor entry/edit screen 221 of FIG. 2B, further details concerning some of the specific, preferred fields, tabs, buttons, etc. shown on screen 221 in FIG. 2B will now be set forth.

[0085] As mentioned, new donor records may be created using screen 221, and pre-existing records may also be edited/modified here. A primary difference in creating new records versus modifying existing ones lies in the fact that the fields shown in FIG. 2B will be empty prior to entry of new record information, as opposed to having been populated by previously entered (or imported) data in the modification sense. As shown in FIG. 2B, the data fields are primarily populated thus generally signifying either a data import or previous donor record entry situation.

[0086] Primarily donor identification data/information, such as the donor's name and/or ID, may be entered/edited in the fields disposed preferably in an upper substantially fixed area 222 of screen 221. However, if this data has come from a previously entered record, the fields in area 222 are

preferably "inactive" as shown by being "grayed-out." Thus, these fields would preferably not be editable directly, rather would be editable otherwise as described below. Other information about a particular donor may then be entered/edited in corresponding fields appearing with respective tabs in the lower data area 224. For example, donor demographics information may be entered/edited in corresponding fields under the "Demographics" tab 231 as shown in FIG. 2B. Other general information such as gender or date of birth, inter alia, would preferably be enterable/editable under the "General" tab 241 (see FIG. 2C). Blood type, CMV, (cytomegalovirus) and HLA (Human Leukocyte Antigen) type, inter alia could be entered/edited under the "History" tab 251 (FIG. 2D). A "Comments" tab 261 (FIG. 2E) could be selected and used for entry of comments about the donor. Allergy information could be entered or edited under an "Allergies" tab 271 (see FIG. 2F). Donor status data could be entered and/or edited under a "Status" tab 281 (FIG. 2G) including such data as, for example, last procedure date, numbers of donations given, over what period of time, etc. Other tabs, such as a "Blood Loss History" tab 291 (FIG. 2H) and/or a "Procedure History" tab 299 (FIG. 2I) could also be used for separate entry of such information. Note, separate pop-up dialog boxes or other alternative screen styles or types (none shown) may be used for prompting for and entering/editing these types of information.

[0087] Note, the information shown and described here in screen 221 may alternatively be optional or mandatory, depending on the desires of the ultimate user; here, usually a blood center. That is, the standard operating procedures (SOP's) of the blood center may be implemented herein to make certain information optional or mandatory, as desired. However, certain information, whether listed here (under the Donor Entry/Edit screen 221) or entered elsewhere (see the Prepare Procedure functionality, described below) may be required by the blood separation/collection assembly 10 prior to initiation and/or completion of a separation/collection procedure. Examples of such information may be gender, height, weight, blood type, and/or pre-count (platelets and/or hematocrit) information (again, see the Prepare Procedure, below). As such, some of this information (e.g., height/weight) would only be enterable/editable, as preferred here, in the procedure preparation portion of the overall process (see below).

[0088] Moreover, as introduced above, all, most, or at least the information required by the blood center may be entered or have been entered previously into the blood center's separate (but communicatively-linked) information system (not separately shown, but see FIG. 1B). Such an information system is separate from the present invention, although these systems may be made to communicate with each other. Thus, such information may be entered into the blood center information system, preferably according to the standard operating procedures (SOP's) of the blood center, and then this information may be transferred (downloaded or uploaded, or otherwise) to the central system 140 of the present invention. This information would then populate the respective fields shown and/or described here relative to the Donor Entry/Edit screen 221. An operator of the present system may then use screen 221 to merely verify the accuracy and/or completeness of this information shown on screen 221 prior to checking-in the donor for the present collection procedure.

[0089] In a presently preferred embodiment, when a blood center information system is used, the transmission of this general sort of donor identification, demographics and commentary information, inter alia, is one-way from the blood center information system to the central server system 140 of the present invention, primarily to maintain SOP's on which types of donor information a blood center may wish to capture. Thus, the operator may continue to operate at reception in a fashion unchanged from before introduction of the present invention.

[0090] Nevertheless, these donor identification data may also be transmitted both ways; namely, from the blood center information system to the central server 140 and/or back to the blood center information system from the central server 140. In such an option, these data may be entered/edited in either system and then be made to update the records of the other system. Note, these donor data communications are discussed here only in terms of the general donor data; not necessarily including feedback information about the results of any particular collection procedure. Such procedural data communications are also considered within the present invention, but are discussed further below.

[0091] First however, more particular descriptions of the preferred data to be entered/edited in screen 221 will now be described.

[0092] As mentioned, in the Demographics tab 231, the operator may enter/modify the donor's national ID, address and telephone number as shown in FIG. 2B. Then, after selecting the General tab 241, the following information may preferably be entered/edited: Gender (Male or Female, neither of which preferably selected by default); Date of Birth (which can be typed in text box or selected using pop-up calendar); Ethnic Background (preferably available via a drop-down list which is editable by selection only, and is preferably created by the System Administrator); and Donor Picture (the default is preferably a generic, genderless icon; however, if a gender is selected using one of the Gender radio buttons, this icon preferably changes to a gender-specific icon the next time the donor record is accessed, provided the operator saved the data before closing the dialog box). The operator can optionally click Update Picture to take donor's photo using an optionally attached digital camera.

[0093] The operator may then optionally click the Donor History tab 251 (FIG. 2D) to view/modify procedure history data for this donor. This tab 251 may contain the following information: Blood Type, CMV, HLA, Hematocrit, and/or Platelet Count. More specifically, the Blood Type may include A+, A-, B+, B-, AB+, AB-, O+, O-, or Unknown; preferably accessible via a drop-down list, editable by selection only; default is preferably Unknown. The CMV Status includes Unknown, Positive, and Negative Radio buttons options; the default is preferably Unknown. HLA Typing options are as follows: the operator may select the HLA Tested check box if HLA testing has been done for this donor; or left unchecked by default. And the A, B, C, D check boxes are disabled unless the HLA Tested check box is selected. Once HLA Tested is selected, the operator can select one or more HLA-type check boxes (A, B, C, and/or D). The Last Hematocrit and the Last Platelet Count are preferably non-editable, generally pre-populated fields from past procedure data or external blood bank information system, if available.

[0094] The operator may then also optionally click the Comments tab 261 (FIG. 2E) to enter/view free-form comments about the donor. To add a comment, the operator clicks the Add Comment button 262. A separate Enter Donor Comment pop-up dialog box (not shown) may then appear, or comments may be made enterable/editable within the work space 263, shown. The operator may then enter a comment in the text box. Note that a comment is preferably not saved in the donor record until the operator clicks the Apply or OK button 229 or 230 in the Donor Entry/Edit dialog box 221 (see more details below).

[0095] The operator may then optionally click the Allergies tab 271 (FIG. 2F) to enter/view donor allergies and associated comments. To view the comments about a specific allergy, the operator clicks the allergy in the Donor Allergies list; associated comments for this allergy appear in a Donor Allergy Comment box. To add an allergy, the operator may click the Add Allergy button. An Enter Donor Allergy pop-up dialog box (not shown) may then appear. A listing of allergies (preferably non-editable and created by the System Administrator) may be made to appear in such a dialog box and the operator may optionally enter a comment pertaining to that allergy in the Allergy Comment box. Note that an allergy is preferably not saved in the donor record until the operator clicks the Apply or OK button 229 or 230 in the Donor Entry/Edit dialog box 221 (see details below).

[0096] The operator may also decide to remove an allergy from the Donor Allergies list. The operator may then click the allergy in the Donor Allergies list, and then click the Remove Allergy button. The allergy is removed from the displayed list; however, the allergy is not permanently removed from the donor record until the operator then clicks Apply or OK button 229 or 230. The operator may decide to enter additional comments for an allergy currently in the Donor Allergies list. The operator clicks the allergy in the Donor Allergies list, and then clicks the Add Comment button. An Allergy Comment dialog box (not shown) may be made to appear. The operator can then enter a comment and click an OK option. The Donor Entry/Edit dialog box 221 reappears, still showing the Allergies tab 271 (FIG. 2F). The allergy listing in the Donor Allergies list is updated to show the new comment. The date and time the comment was created, as well as the user ID for the user who was logged on when the comment was created, will preferably appear with the comment in the Donor Allergy Comment box.

[0097] The operator may then optionally click the Status tab 281 (FIG. 2G) to enter/view the following donor status information: Donor Status—Active or Inactive; Donor Category (a drop-down list, preferably created by the System Administrator); Donor Since Date—date the donor started donating (preferably defaults to first procedure date, if not modified, which can be typed in text box or selected using a pop-up calendar); Last Visit Date—last date the donor attempted to donate (defaults from system records, preferably non-editable except by the System Administrator); Last Procedure Date—the last date the donor actually did donate (default from system records, non-editable except by the System Administrator); Last Contact Date—last date that the center contacted the donor (can be typed in text box or selected using pop-up calendar, default is preferably the current date).

[0098] The operator may then optionally click the Blood Loss History tab 291 (FIG. 2H) to view the total volume of blood the donor has lost from apheresis (not whole blood) activities for the previous 12-month period. All of the data in this tab is preferably non-editable in this module. It is downloaded as run data from the apheresis collection system 10 (preferably a Trima® system 10) for procedures run for this donor, and/or entered by an operator during procedure finalization (see below). The tab 291 preferably shows the Total Blood Loss the total volume (preferably in milliliters) of blood the donor has lost from apheresis (not whole blood) activities for the previous 12-month period; and a Procedure table which shows blood loss for apheresis procedures for which a procedure record exists in the central server system 140. Each procedure is preferably listed in a separate row in the table. The operator may need to scroll horizontally or vertically to view some of the data. For each procedure, the table preferably shows the following:

[0099] Procedure Date—The date the procedure was run.

[0100] Product RBC—The volume of RBC product collected during the procedure (total RBC volume less anticoagulant volume). This information is preferably determined based on the procedure that was run and the donor's hematocrit.

[0101] Sample RBC—The volume of sample RBCs collected during the procedure. This volume is either the default value set by the Administrator during system setup or a value entered by an operator during procedure finalization, according to the facility's SOPs (see the Finalize Procedure Record description below).

[0102] Residual RBC—The volume of residual RBCs remaining in the tubing set after the procedure. This information is determined based on the tubing set type, the procedure that was run, the donor's hematocrit, and whether or not rinseback was completed for the procedure.

[0103] Other RBC—Any other RBC volume (for example, estimated volume of a spill), entered by the operator in the Finalize Procedure Information dialog box, Blood Loss tab, according to the facility's SOPs. (see the Finalize Procedure Record description below).

[0104] Product Plasma—The volume of plasma product collected during the procedure (total plasma volume less anticoagulant volume). The information is determined based on the procedure that was run and the donor's hematocrit.

[0105] Sample Plasma (not shown in FIG. 2H; scrolled off the right side of the screen)—The volume of sample plasma collected during the procedure. This volume is either the default value set by the Administrator during system setup, or a value entered by an operator during procedure finalization, according to the facility's SOP's (see the Finalize Procedure Record description below).

[0106] Residual Plasma (not shown in FIG. 2H; scrolled off the right side of the screen)—The volume of residual plasma remaining in the tubing set

after the procedure. This information is determined based on the tubing set type, the procedure that was run, the donor's hematocrit, and whether or not rinseback was completed for the procedure.

[0107] Other Plasma (not shown in FIG. 2H; scrolled off the right side of the screen)—Any other plasma volume (for example, estimated volume of a spill), entered by the operator in the Finalize Procedure Information dialog box, Blood Loss tab, according to the facility's SOPs. (see the Finalize Procedure Record description below).

[0108] The operator may then optionally click the Procedure History tab 299 to view product information for all procedures run for this donor since the donor record was created in the present system 140. The tab 299 shows product information only for apheresis procedures for which a procedure record exists in the database 142. All of the data in this tab is preferably non-editable. It is downloaded from the apheresis system (preferably a Trima® system) 10 run data for procedures run for this donor. The operator may need to scroll horizontally or vertically to view some of the data. For each procedure, this tab 299 preferably shows the following:

[0109] Procedure Date—The date the procedure was run.

[0110] Platelet Yield—The yield of platelets collected during the procedure.

[0111] Plasma Volume—The volume of plasma collected during the procedure (plasma product volume plus anticoagulant volume).

[0112] RBC Volume—The volume of RBCs collected during the procedure (RBC product volume plus anticoagulant volume).

[0113] Various alternative data entry/editing actions may also be preferred. For example, at any time while using the Donor Entry/Edit dialog box 221, the operator may click the Apply button 229 (see FIGS. 2B-2F, e.g.) to save all to-date changes to the donor record, without exiting the dialog box. Similarly, at any time while using the Donor Entry/Edit dialog box 221, the operator may click the Cancel button 228 to cancel the current entry session. The system 140 may then prompt the operator to confirm the cancellation. If cancellation is confirmed, the system may lose all unsaved changes and closes the Donor Entry/Edit dialog box 221. A Help button 227 is preferably also provided to present a corresponding help screen (not shown) when desired.

[0114] If the facility determines that a donor record no longer needs to be in the central database 142, the record can be permanently removed. This option is preferably only available when an operator with a high level clearance such as a System Administrator user role or the like is logged on to the system. This Administrator or high level operator may then search for and display the donor record in the Donor Entry/Edit dialog box 221, as described and then click the Remove button 226 (see e.g., FIG. 2B). A warning may first be made to appear, informing the operator that the record will be permanently removed from the database 142. If removal is still desired a Yes confirmation button (not shown) may be selected. The following may then occur: 1) both the warning message and the Donor Entry/Edit dialog

box 221 may be closed; 2) the Search Results box 204 in the Select Donor task window 201 (see FIG. 2A) would no longer show a listing for the removed donor; 3) the donor record would preferably be permanently removed from the database; and/or 4) an internal record for this donor may be retained elsewhere in the system for reporting reasons.

[0115] Moreover, at any time while using the Donor Entry/Edit dialog box 221, the operator may change the donor's name, while retaining the current donor ID. To do so, the operator would preferably click the Edit Donor Name button 223 (see e.g., FIG. 2B) in the Donor Entry/Edit dialog box 221. An Edit Donor Name dialog box (not shown) would preferably be made to appear, displaying all previous names used by the donor, as well as the date the name was changed and the operator who was logged on to the system when the name change was made. The operator may then enter a new name for the donor in the Last Name, First Name, and/or Middle Name boxes, and conclude with an OK option (not shown). The Donor Entry/Edit dialog box 221 would then reappear, showing the changed name. The operator can still also decide to not change the name by selecting a Cancel option in the Edit Donor Name dialog box (not shown) to retain the current donor name; whereby, the Donor Entry/Edit dialog box 221 would reappear, showing the unchanged name. Note that a changed name is not saved in the donor record until the operator clicks the Apply or OK button 229 or 230 in the Donor Entry/Edit dialog box 221.

[0116] Similarly, at any time while using the Donor Entry/Edit dialog box 221, the operator may change the donor's ID, while retaining the current donor name. To do so, the operator would click the Edit Donor ID button 225 (see FIG. 2B) in the Donor Entry/Edit dialog box 221. An Edit Donor ID dialog box (not shown) would preferably be made to appear, displaying the current donor ID. The operator could then enter a new ID for the donor in the New Donor ID box, and click an OK button (not shown) to save the ID change. The Donor Entry/Edit dialog box 221 reappears, showing the changed ID. The operator can also decide not to change the donor's ID, and click a Cancel option in the Edit Donor ID dialog box (not shown) to retain the current donor ID; in this case, the Donor Entry/Edit dialog box 221 would again reappear, showing the unchanged ID. Note that a changed ID is not saved in the donor record until the operator clicks the Apply or OK button 229 or 230 in the Donor Entry/Edit dialog box 221.

[0117] At any time, the operator can search for and select the record for any donor who is already checked in to the system. However, if the donor is already checked in to the system, the following fields, inter alia, in the Donor Entry/Edit dialog box 221 may be preferably disabled and therefore cannot be modified: General tab: Gender; History tab: Blood Type; Status tab: Donor Status.

[0118] Once the appropriate/desired donor data is satisfactorily entered, edited and/or verified using screen 221 (FIGS. 2B-2I), the donor may then be checked-in to the next step in the process, the Prepare Procedure step/sub-procedure (described below). Donor check-in may be accomplished from any view of screen 221 by clicking the "OK" button 230 (or another appropriately labeled button, e.g., "Check-in" if so provided, not shown). This may then send the donor information to the Prepare Procedure portion of the software application (e.g., to the Prepare Procedure

software module, if the software is so modularized as is preferred). Alternatively, a pop-up dialog box (not shown) can be made to appear for confirmation that donor check-in is desired. "Yes" or "No" options may be provided in such a pop-up dialog box to confirm the operator's desires. Clicking the "Yes" option will then pass the donor information to the Prepare Procedure Step, as described. Note, clicking the "No" option will provide for not passing the donor information to the next procedural step; however, it may be made to either save all edited/entered information while exiting the Donor Entry/Edit screen 221, or it may be made to call up a further pop-up window to confirm whether the edited/entered information should be saved to the central memory 142 before exiting the Donor Entry/Edit screen 221. Note also that, as will be described below, the donor data entered/edited via screen 221 may be made further enterable/editable at later stages of the overall procedure after initial check-in, still preferably through use of a screen 221, or the like. Thus, provision (preferably through clicking the Select Donor icon 207 in bar 205; see FIG. 2A) may be made to return to screen 221 or the like at later stages of the procedure to enter new data or modify existing data, as may be desired. However, at such later stages, a check-in option would not preferably be made available if (as would be true in such a situation) the donor had/has already been checked-in. Thus, clicking the "OK" button 230 (see FIG. 2B, e.g.) would only save the information to the donor record in memory 142 and not proceed to a "Check-in" dialog box, if used (not shown).

[0119] FIG. 3A shows the next step in the overall general component collection procedure which would appear after donor check-in is completed as described above. This next step corresponds generally with the shown display screen 301 which would have been accessed via clicking on the Prepare Procedure icon 208 in the procedure icon area 205. This next step in the data entry/manipulation process shows, via the display screen 301, the donors who have been checked into the system and are now ready for selections of the desired collection procedures to be performed. The work area 202 of screen 301 in FIG. 3A then preferably displays a listing of donors (via a text list (not shown) or by representative icons as shown, or otherwise (not shown)), which have been checked-in according to the above-described procedure(s). This grouping or listing of checked-in donors may also be referred to as a "donor queue." A donor may then be selected from this queue by clicking the corresponding icon 302 or 303, for example. Once the donor is selected in screen 301 (selection being indicated by distinctive shading, see icon 303 in FIG. 3A), the next step can be accessed by clicking the "Prepare" button 304 in the main work area 202, or, in an optional embodiment, by again clicking the "Prepare Procedure" icon 208 in the icon area 205. Note, a "Remove" button 305 could alternatively be selected to remove the donor from the Checked-in Donor Queue, (i.e., from the work area 202) if desired. Also, help may be obtained at any time by selection of the "Help" button 306. Note, in a preferred embodiment, the donor icon(s) 302 and/or 303 may include the donor's photo (i.e., as introduced above, the computer/database system 140 may also be equipped with a digital camera as is known in the art of computer systems generally).

[0120] There may be at least two general and perhaps overlapping preferences for separating the Donor Check-in functionality from the Prepare Procedure functionality. Specifically, a first such preference may derive from the three

room scenario suggested/described above, wherein a donor may be greeted by a receptionist or receptionist-type of operator in a "Reception" room or area. Then, the donor information described generally above (see FIGS. 2A-2I, e.g.) may be entered and/or edited and/or verified at such a "Reception" point of the overall procedure. The donor may then be moved to a second, discrete room where a second, discrete operator may perform the Procedure Preparation steps described hereinbelow. These rooms/areas may be separate physically or rather may not actually be separate at all, depending upon the blood center and its preferred operating procedures and facility arrangements. The operators may also not be discrete; however, the second, likely overlapping preference for the functionality separation may be that there are two separate operators and the second operator may have different technical skills and/or qualifications from the first operator, i.e., the second operator may be qualified to run the actual collection procedure while the first, reception operator/person may not. Thus, by separating these functionalities (even if the "rooms" are not separated), the reception person or the reception area computer may be given access limited only to the Select Donor icon functionality, for example. At the same time, the perhaps higher qualified collection operator may be relieved of the data entry/edit tasks associated with initial check-in procedures.

[0121] As a result of finishing the previous steps (data entry modification and donor check-in), the Prepare Procedure portion of the overall process may be performed next. As shown in FIG. 3B, a "Prepare Procedure" sub-procedure, preferably a "Prepare Procedure" Wizard, as depicted by a first Wizard display screen 321, may substantially automatically lead the operator through the procedure preparation process. Note, a wizard as known in the art generally, may be a software module or sub-procedure which includes a series of screens used to accomplish a particular task or operation. Note, this "Prepare Procedure" wizard screen and/or other such screens (as follow) may be sub-windows or full window-sized displays.

[0122] In particular, as shown here, respective screens 321, 331, 341, and 351 of respective FIGS. 3B, 3C, 3D, and 3E represent substantially sequential wizard screens accessed initially by the selection of the "Prepare" button 304 (after selection/highlighting a particular donor icon, e.g. icon 303) of screen 321 in FIG. 3A. These wizard screens 321-351 are then sequentially accessed, one to the next, by the selection of the respective "Next" buttons 322 (see lower portions of screens in FIGS. 3B and 3C, e.g.). Backtracking, in reverse order, of these wizard screens is also available by selection of the respective "Back" buttons 323, disposed preferably adjacent the "Next" buttons 322. Other general wizard buttons such as the "Help" button(s) 324, the "History" button(s) 325 and the "Cancel" button(s) 326 may be selected at any general point in this process to obtain respectively assistance/information, a history of data entry/edits (and/or optionally displayed screen views 321-351, e.g.) and/or to cancel the Prepare Procedure wizard at any time.

[0123] Further details of preferred process for using these preferred and like screens will now be set forth.

[0124] The operator is presented with the first page of the "Prepare Procedure" module/wizard/ sub-procedure, the Donor Identification page 321 as shown in FIG. 3B. This page shows the donor's name, donor ID, date of birth (DOB), and photo (if previously taken and/or saved in the database 142). This page allows the operator to confirm the

donor's identity and, optionally, to take or update a photo of the donor. An "update picture" button 328 may be supplied for providing a new or updated photo. Field specific behavior of these items is preferably as follows: the "Donor Name" is pre-populated with first and last name from the donor record data, and is preferably not editable here. The "Donor ID" is also pre-populated, and preferably not editable. The "Date of Birth" field is pre-populated using localized format, and not editable. And, the "Donor's photo" is also preferably pre-populated to further assist the operator confirm the proper donor is present for this procedure being prepared. If such a photo is not available for this particular donor, a generic male or female icon may be displayed. The operator may then click the "Next" button 322 to proceed to the next page of the wizard.

[0125] A Unit Number text box 329 may also be disposed in either of screens 321 or 331 (or elsewhere, see FIG. 3B). A Unit Number is preferably a required field entry. The operator may enter the unit number either by typing the number in the Unit Number box 329, or by using a barcode reader (not shown, e.g., by highlighting the unit number field 329 and then using the bar code reader to scan the supply bar code which would then populate this field 329). The unit number may be supplies related information or taken therefrom as related to the tubing set type used, or the bag identifiers to be used. The Directed Donor and HLA matched boxes 330 are further alternative fields which could be entered/edited at this (or a later) stage of the procedure. These fields are directed to noting whether this donor is providing a donation for a specific pre-identified recipient, and the HLA match box merely records whether the HLA types have already been matched for such a directed donation per pre-existing techniques. The operator may then click the Next button 322 to proceed to the next page, or the Back button 323 to return to the previous page.

[0126] Then, as shown by the display screen 331 in FIG. 3C, gender, height, weight, hematocrit and platelet pre-count parameters will preferably be entered, if not already populated in the respective fields 332, 333, 336 and 337 as previously entered in and thus disposed in the database 142. In fact, even if these parameters are previously entered, these fields in this screen 331 may be made mandatorily re-entered here, or at least re-confirmed before the system 140 may allow the operator or donation process to proceed (note, if re-entered here, it may be that this data re-entry could rewrite the database information at this point or at the end of the collection process as part of the entire record which is saved to the central database 142 at that time). The other fields shown in this FIG. 3C are preferably entered as well, but may be made optional. As introduced above, and as will be understood from further description below, the required fields may be populated with historical data until the current lab values come back.

[0127] More particularly, the operator is presented with the Donor Information page 331 of the wizard, see FIG. 3C. Donor "vitals" are taken and entered on this page. The following items are preferably displayed on the Donor Information page 331. The Donor's Gender is preferably pre-populated in field 332, required, and editable via selection: Male or Female. The Donor's Height and Weight are preferably also pre-populated (see fields 333) with the last value (from database 142, if available) in localized units, editable, and required. The value written to the database will

indicate if the value was changed. The "TBV" (Total blood volume) in field 334 is dynamically calculated (non-editable), based on the Height, Weight, and Gender fields 332, 333. The Donor Blood type is also preferably pre-populated in field 335, either from database 142 or (if unknown for this donor) pre-populated with Unknown. This field is preferably editable via a selection: O+, O-, A+, A-B+, B-, AB+, AB-, or Unknown.

[0128] The Hematocrit/Hemoglobin field 336 is labeled either Hematocrit as shown or Hemoglobin (not shown), based on the system setup that is defined by the System Administrator. Data in this field is required, and may be entered by the operator, or a default value may exist. If the Administrator configures this field to use a default value, and historical data of the configured type is available for this donor, the field is pre-populated with the historical data. The type of historical data used as the default may be configured by the Administrator to be one of the following types: Average of last three pre-procedure values; Last visit's pre-procedure value; No default value; Gender-based default value; or blood center chosen default value. The value written to the database and displayed on the page indicates if the value is one of the configurable defaults above or if it is a measured value entered by the operator.

[0129] The Platelet Pre-count field 337 is also entered here. Data in this field 337 is required, and may be entered by the operator, or a default value may exist preferably as defined by the Administrator. If the Administrator configures this field to use a default value, and historical data of the configured type is available for this donor, the field is pre-populated with the historical data. The type of historical data which may be used as the default may be configured by the Administrator to be one of the following types: Average of last three pre-procedure values; Last visit's pre-procedure value; No default value; Gender or Center-wide default. The value written to the database and displayed on the page preferably indicates if the value is one of the configurable defaults above or if it is a measured value entered by the operator.

[0130] In addition to the above, preferably-required items, the operator may enter the appropriate optional donor vitals (see generally fields 338); Temperature (an optional field in localized units: Fahrenheit or Centigrade); Blood pressure; and Pulse (optional fields).

[0131] When all required information (and any optional information the operator chooses to enter) has been entered, the operator clicks the Next button 322 to proceed to the next page 341 or 351 (FIGS. 3D or 3E), or the Back button 323 to return to the previous page 321 (FIG. 3B). Note, if a required field does not have an entered value, an attempted click of the Next button 322 will preferably present a prompt that a value must be entered in this field before the wizard can proceed to the next page. Note, if the operator enters a value in a field that is above or below the allowable limits for that field (hard limits), or a value that is unusually high or unusually low (soft limits), a message will preferably be made to appear. If this is a soft limit, the message informs the operator that the value is outside the limits and asks if the operator wishes to proceed. The operator may click a Yes option to use the value and proceed, or No to enter a new value. If this is a hard limit, the operator may be required to enter a new value in order to proceed. Also, if the blood

center uses a blood bank information system, a warning message will preferably be made to appear when the operator changes a donor demographic field on the Donor Information page 331 (FIG. 3C). This warning would indicate that the demographics data must be changed in the blood bank information system to be permanently saved.

[0132] In a simplified process (usually for operators with lower qualifications, or wanting or needing fewer choices), after the operator has clicked the "Next" button 322 (FIG. 3C), the operator is then presented with the Target Procedure page 351 (FIG. 3E) of the wizard. Screen 341 (FIG. 3D) is skipped in this simplified procedure. The operator may then accept the recommended target procedure (shown highlighted with a rightward-pointing arrow icon 355 in FIG. 3E). Note that the target procedure is obtained by the system 140 running the apheresis time and/or product yield optimization routines such as are run on the Trima® collection systems 10 (and as described below, see description accompanying FIGS. 7-10) in the present system application, and that the parameters for the highlighted procedure are preferably shown above the procedure list. The operator may then optionally click the Finish button 352 (FIG. 3E) to complete the "Prepare Procedure" apheresis procedure selection process.

[0133] Note, the running of the apheresis optimization routines by system 140 preferably involves the use of data either from storage in the central memory 142 and/or as input into system 140 via input devices 149 at any station 148 (as described hereinabove) preferably through use of the sub-procedures described herein (i.e., using the screens shown in FIGS. 2A-21 and 3A-3C) and communicated through subsystem(s) 146 and then manipulated by the manipulation device 144. The manipulated data may then result in optimized data which can then be interpreted by the system as representing a system preferred target procedure (or procedures) such as is shown in FIG. 3E. Again, optimized data would provide usually either the largest yield in a certain time, or the shortest time to reach a minimum yield (see FIGS. 7-10, below). Other manipulations may provide for procedures which may not be either time or yield optimized, but which a blood center may find otherwise perhaps more desirable, such as platelet (or other component) preferences no matter what the optimization program(s) might suggest. Thus, the system 140 and manipulation device 144 can manipulate the donor statistics (vitals, etc.) against a large plurality of procedure types and compare with blood center prioritizations to obtain various sorts of procedure lists such as that shown in FIG. 3E. Preferably, the optimal procedure (optimized or merely manipulated according to system administrator preselections) may be returned with the rightward-pointing arrow icon 355; however, preferably also other procedures will be listed also with various icon representations to signify prioritization. For example, as shown in FIG. 3E, numerous procedures are shown with a circle with a diagonal line which here preferably represents procedures which are not available due to physical (and/or safety) constraints such as the donor not meeting a minimum hematocrit or total blood volume preferred therefor. Green circles, *inter alia*, can be used to signify less than optimal procedures which would nevertheless be available for this donor to be subjected to. Question marks could be used to signify procedures which could be

available options if the parameters (e.g., time, lab values, etc.) were to change (i.e., if more time were allowed for a collection).

[0134] Note several alternative actions may be presented. For example, in some instances it may occur that more than one target procedure may be indicated, whereby the operator may then choose the preferred procedure. Or perhaps the donor may be disqualified such that no procedures appear available. The donor can be disqualified for the donation based on the donor vitals or screening questions. In this situation, the operator may press the Cancel button 326 on any page in the Prepare Procedure Wizard to discontinue the prepare procedure process. The operator may then remove the donor from the Checked-in Donor Queue, as described in the "Prepare Procedure" sub-procedure above.

[0135] Otherwise, the donor may be unable to donate if the central system 140 cannot determine a valid apheresis procedure to run for this donor. If this is the case, the central system 140 preferably displays a dialog box (not shown) explaining the reason a procedure cannot be determined. Based on the blood center's policy, the operator may ask the donor if the donor can stay longer. The operator may then extend the procedure time, as described in the "Adjust Donation Time" alternative sub-procedure below.

[0136] As noted, the operator may adjust the donation time. If the donor can only stay longer or perhaps only a certain limited amount of time, the operator may change the default maximum procedure time by clicking the Adjust button 353 (FIG. 3E). The operator is presented with the Procedure Adjustments dialog box 361 (see FIG. 3F), in which the operator may enter a new maximum procedure time. The operator may then click the OK button to return to the Target Procedure page 351 (FIG. 3E) of the wizard. If the maximum procedure time is changed, the Target Procedure page is re-optimized and possibly recommends a different procedure. It is also possible that there are no procedures available as a result of the time change.

[0137] Similarly, the operator may adjust the tubing set type availability. If only certain tubing sets are available, the operator may change the tubing set type availability by clicking the Adjust button 353. The operator again is presented with the Procedure Adjustments dialog box 361, in which all three tubing set types (e.g. Grey, White, and Black options for the Trima® apheresis systems 10; other optional set types and/or designations may be used for other blood processing systems 10, as desired) are checked by default. The operator may uncheck one or more tubing set types. The operator may then click the OK button to return to the Target Procedure page 351 of the wizard. If the tubing set type availability is changed, the Target Procedure page is re-optimized and possibly recommends a different procedure. It is also possible that there are no procedures available as a result of the tubing set availability change.

[0138] Note, the operator may also select certain different procedures in the procedure list shown in screen 351 (FIG. 3E). The operator may select a procedure with an icon indicating that the procedure can be run for this donor (though perhaps not the optimal procedure according to the system 140), or a procedure with an icon indicating that the procedure can be run for this donor, but only if the donor's actual hematocrit and/or platelet precount change significantly from the values entered in screen 331 (or the default

values used in screen 331). In any event, preferably the operator cannot select a procedure with an icon indicating that the procedure cannot be run for this donor. Note that when the operator selects a different procedure in the list, the parameters for the selected procedure are shown above the procedure list. Note, the operator may also view any of the listed procedure details. To do so, the operator may double-click a listed procedure to view a Procedure Details dialog box (not shown), which may provide more detailed information about the procedure. The operator may double-click either the currently-selected procedure, or any other procedure in the list. The operator may click an OK button to close the Procedure Details dialog box (not shown) and return to the Target Procedure page 351 of the wizard. If the operator double-clicked a procedure other than the currently-selected procedure, the procedure that the operator double-clicked would now preferably be selected (e.g., highlighted) in the Target Procedure page 351.

[0139] Note also that an operator may select different donation options, preferably after the step depicted by screen 331 (FIG. 3C), but prior to the step depicted by screen 351 (FIG. 3E). Preferably, however, this option would be limited to higher security users preparing the donation. Then an additional page 341 (FIG. 3D) would appear, allowing finer control of the donation. This page 341 would be presented only to individuals with the higher privilege level. The following two steps could be added for this operator. The operator would choose the blood product types eligible for this donation (e.g. platelets, RBC's or plasma). These choices would be used to disqualify one or more product types from being collected. By default, all product types are preferably eligible for a donation. Thus, a check in the corresponding box in area 342 of the "Select Products and Configuration" page 341 would indicate that the product type may be collected. If the corresponding box is unchecked, any procedure that would collect this product type is disqualified in the Target Procedure page 351 (FIG. 3E). The three choices are platelets, plasma and red blood cells. Any combination hereof may be checked. As shown in area 343, the operator may also select alternative apheresis system configurations or product focus lists to utilize for this donor's donation. Note that these changes would preferably only apply to this donation. For Focus Lists, the operator may select a product focus list from this drop-down list. The center-wide default focus list is preferably pre-populated in this drop-down list. All focus lists that have been defined by the Administrator will then appear in this drop-down list. For Machine Configuration, the operator may select an apheresis system machine configuration from this drop-down list. The center-wide default machine configuration is preferably pre-populated in this drop-down list. All machine configurations that have been defined by the Administrator will then appear in this drop-down list.

[0140] At any point while using the Prepare Procedure Wizard, the operator may click the History button 329 (see FIG. 3C) to view the donor's record. When the operator clicks the History button 325, the Donor Entry/Edit dialog box 221 (see FIGS. 2B-2I) appears, showing all information in the donor record. To return to the Prepare Procedure Wizard, the operator clicks the OK button in the Donor Entry/Edit dialog box 221.

[0141] Note, the sub-procedure depicted by the screens in FIGS. 3B-3E may be known generally as "screening" in suggesting that these functions may be performed in the second room, the "Screening" room, of the three room model described above.

[0142] Then, in the next procedural step as shown by the display screen 401 in FIG. 4A, the donor may be assigned to a blood processing machine 10. Screen 401 may be accessed via a button such as the "Finish" button 352 appearing on the last page 351 (FIG. 3E) of the "Prepare Procedure" wizard/sub-procedure, or more preferably by clicking the "assign machine" icon 209 appearing in the icon work area 205 (see FIGS. 2A and 4A, e.g.). Assigning a donor to a machine may be a simple matter of clicking and dragging the donor's icon 402 (with or without photo) to an available Trima® or like apheresis machine icon 404 as shown in the respective left and right portions 406, 408 of the main work area 202 in screen 401.

[0143] Note however, that any particular donor will preferably not be available (i.e., no icon will preferably show up) in the icon list 406 (also labeled as a "Donor Assignment Queue") until completion of the "Prepare Procedure" sub-procedure (i.e., as accessed using the "Prepare Procedure" icon 208, e.g.) as described for the wizard module in FIGS. 3B-3F. However, after the "Prepare Procedure" sub-procedure is completed, preferably after the clicking of the "Finish" button 352 on the last screen 351 of the wizard (see FIG. 3E), a donor icon for that donor, such as icon 402, e.g. is preferably automatically generated and automatically placed in the icon list 406. Thus, the donor, as represented by the icon, is then ready to be assigned to a particular apheresis assembly 10.

[0144] In more detail, to do so, the operator will first preferably double-click the Assign Machine task icon 209 in the main window task bar 205, or, alternatively, the operator may select the Assign Machine element (not shown) from the Tasks menu 216. The Assign Machine task window 401 is then displayed, showing two panes: the Donor Assignment Queue 406 and the Machines list 408. The Donor Assignment Queue 406 shows donor icons (e.g., icon 402) for all donors who are ready for machine assignment. Donor icons are preferably ordered in the queue based on the time an operator finished using the Prepare Procedure Wizard (see above) to prepare a procedure for the donor. The donor for whom the Prepare Procedure Wizard was finished the longest ago preferably appears at the top of the queue. The donor for whom the Prepare Procedure Wizard was finished most recently preferably appears at the bottom of the queue. The Machines list 408 shows an icon for each apheresis system in the facility that is enabled in the current network. To help the operator make a decision about which machine to select for a donor, the following information is preferably displayed as part of each machine icon: run status; time remaining if a procedure is currently running on the machine; name of the next donor queued for the machine; machine communications status (online or offline).

[0145] To assign a donor to a machine, the operator preferably selects a donor icon from the Donor Assignment Queue 406 and drags it to a machine icon in the Machines list 408. Alternatively, the operator may select a donor icon 402, e.g., (by highlighting/clicking it once, not shown) and a machine icon 404 and then click the Assign button 410 to make the assignment. A confirmation dialog box (not shown) may then be displayed with "Yes" and "No" options to ask the operator to confirm the assignment. If the operator clicks the "Yes," option, the system may then close the confirmation dialog box, and, in the Assign Machine task window 401, the following preferably occurs: the donor icon

402 is removed from Donor Assignment Queue 406 and the machine information in the Machines list 408 is updated to show that the donor is assigned to the machine. If the operator clicks the option "No," option, the system closes the confirmation dialog box, and, in the Assign Machine task window 401, the following occurs: the donor icon 402 remains in the Donor Assignment Queue 406, and the machine information in the Machines list 408 is unchanged. After a short delay, the donor information (and photo, if available) appear on the apheresis system. In addition, the donation-specific apheresis system configuration is in effect on the machine. At this point, the operator may continue using the Assign Machine task window or select another option in the system main window.

[0146] Some alternative process flows for donor/machine assignments are as follows.

[0147] It may be possible that all machines 10 are non-functional. If this is the case, the operator (or another member of the facility's staff) will need to fix the problem at those machines 10, to make at least one machine 10 available. If this is not possible, the operator may be required to remove all donors from the Donor Assignment Queue, as described below.

[0148] At any time prior to machine assignment, the operator may edit the information about a procedure by selecting the donor's icon (e.g., icon 402) in the Donor Assignment Queue 406 in screen 401 and clicking the Edit button 405. The Prepare Procedure Wizard (see FIGS. 3B-3E) appears, allowing the operator to edit the procedure information. Once the operator clicks Finish 352 on the last page 351 of the wizard, the Assign Machine task window 401 is redisplayed. (Alternatively, the operator may redisplay the Assign Machine task window 401 by clicking Cancel 326 on any page of the wizard; however, in this case, the modifications that were made in the wizard are discarded.)

[0149] At any time prior to machine assignment, the operator may remove a donor from the Donor Assignment Queue 406 by selecting the donor's icon (e.g., icon 402) in the Donor Assignment Queue 406 and clicking the Remove button 407. A Confirm Remove Donor dialog box (not shown) may be made to appear, allowing the operator to enter a reason for the removal and/or select a reason from a predefined list (preferably created by the Administrator). Once the operator clicks the OK option in the Confirm Remove Donor dialog box (not shown), the donor's icon is removed from the Donor Assignment Queue 406.

[0150] The operator may also unassign a donor from an apheresis system 10 under the following conditions; namely, if another donor is currently donating on the machine, and the donor the operator wants to unassign is queued to donate on the machine, and/or if the machine is offline. To unassign the donor, the operator may click the machine icon 404 in the Machines list 408 and then click the Unassign button 412. The machine icon 404 returns to its previous state. In addition, an icon (e.g., icon 402) for the unassigned donor reappears in the Donor Assignment Queue 406. To distinguish this donor from donors who have not yet been assigned to any apheresis system 10, this donor's icon is gray. The donor may then be reassigned to an apheresis system 10 as described in the basic procedural flow, or removed from the Donor Assignment Queue 406 as

described in the "Remove Donor" alternative flow, above. Note: the Unassign button 412 is disabled when no machine icon is selected. If the operator then clicks a machine icon (such as icon 402, inter alia) the Unassign button 412 will remain disabled, the unassign feature not being available for that machine at this time.

[0151] If a donor is assigned to an apheresis system 10, but then is dismissed at the apheresis machine 10 using, for example, the touch-screen display 199, the machine icon 402 in the Machines list 408 in the Assign Machine task window 401 returns to the "Ready for Donor" state. In addition, an icon (e.g., icon 402) for the dismissed donor reappears in the Donor Assignment Queue. To distinguish this donor from donors who have not yet been assigned to any apheresis system 10, this donor's icon is "grayed-out". The donor may then be reassigned to an apheresis system 10 as described in the general sub-procedure for Assign a Donor, or removed from the Donor Assignment Queue 406 as described in the "Remove Donor" alternative sub-procedure, above.

[0152] After assigning a donor to an apheresis machine 10 as described, the display screen 421 shown in FIG. 4B appears on the corresponding display area (e.g., touch-screen 199, if used) of the assigned blood component apheresis assembly 10 itself. The operator may then either confirm the information appearing on the apheresis screen 421 by depressing the "continue" button 422, or the like; or the operator may touch/push the box 423 marked with an "X" to decline the donor assignment, thus sending the donor data back to the central system 140 and figuratively send the donor back to the "waiting/screening" room. The apheresis screen 421 shown here may have touch-screen capabilities as understood in the art, or may accept input through other means such as mouse driven cursors, inter alia, which are within the skill of the art.

[0153] Note, it is still also conceived that though perhaps not preferable, there may be situations in which the system may be configured to allow the operator to enter data directly on the apheresis machine 10 itself and then perform data manipulation and/or optimization as is known for many existing machines 10 without requiring the use of a central computer/database system 140. Nevertheless, it is also conceivable that in such a situation it may be preferable to still collect data at a centralized system 140 for database or reporting purposes.

[0154] After the download of the information from the computer/database system 140 to the actual apheresis machine assembly 10 as described, then the computer/database system 140 may preferably only be used for monitoring and/or reporting. This follows a preference that all actual apheresis control during a procedure remains resident in the apheresis machine 10 itself. It is possible, however, if not preferable, to have computer/database system 140 exert control over apheresis machine functions, including process control manipulation and optimization, during procedures, as well. In either case, as shown in screen 501 of FIG. 5A, it is at this point that the computer/database system 140 can be used to monitor the procedure(s) occurring on one or more apheresis machines 10. All procedure interventions again would preferably occur directly on the apheresis machine 10 through its touchscreen 199 or other input mechanism as known in the art.

[0155] In monitoring mode, real time monitoring of procedures on the centralized computer/database system 140 allows the administrator to know the status of collection of any or all machines 10 at a glance. This can help with scheduling and management. Alarm states may also be displayed and/or all other occurrences and/or activities of each machine may be recorded (not specifically shown). As shown in screen 521, FIG. 5B, detailed data information can be called up to assess the status of a procedure. More details concerning these display screens and the information thereof will now be set forth.

[0156] In operation the operator preferably double-clicks the Monitor Procedure task icon 210 in the main window task bar 205 (FIGS. 2A and 5A), or, alternatively, the operator may select the "Monitor Procedure" element (not shown) from the Tasks menu 216.

[0157] The present system 140 preferably provides users with the ability to view the status of all procedures currently running on machines 10 connected on the local machine network 146A (see FIG. 1C), as well as procedures which have completed on a machine 10, but for which not all required finalization data has been added to the procedure record. Status information is supplied continuously from each machine 10 to visit status table (not shown) in the central database 142. The Monitor Procedure module scans an internal visit status table recurrently; the Monitor Procedure task window 501 is preferably updated based on the current data in the internal visit status table. Using the Monitor Procedure function, operators can enter a comment about a procedure; enter finalization data about the procedure, such as supplies data and operator roles; view more detailed information about a procedure's status; or force record completion, inter alia.

[0158] The basic flow for the monitoring sub-procedure is as follows. Two different general types of procedures are displayed in the Monitor Procedure task window 501; namely Active and Pending procedures. In Active procedures, all of the procedures currently running on machines 10 connected to the machine network 146A, including active procedures currently in an alarm state, are shown. Pending procedures are procedures that have been completed on the apheresis machine 10, but for which not all required finalization data may have been entered in the procedure record. Note, procedures are considered active from the time that donor and procedure data is downloaded from central system 140 to an apheresis machine 10, until the time that the central system 140 receives indication from the apheresis machine 10 that either the procedure run has been completed, or the operator has indicated on the apheresis machine 10 that the procedure run is incomplete.

[0159] In the Monitor Procedure task window 501, procedures are preferably displayed in table format (as shown in FIG. 5A). For each procedure, the following information is preferably displayed: machine ID; collection stage and status; donor name; procedure name; and the time remaining. In addition, an icon (e.g., icon 503) next to each procedure description may preferably indicate if the procedure is in an active, pending, or even an alarm state.

[0160] The operator may then optionally select a procedure in the list and then click the Add Comment button 505 to enter a comment in the procedure record for that procedure. An Enter Procedure Comment dialog box (not shown),

may then be made to appear. The operator can then select a comment from the pre-configured comment list (preferably created by the System Administrator) and/or enter a free-form text comment entry.

[0161] The operator may then optionally select a procedure in the list and then click the Procedure Information button 507 to enter data about the procedure, such as supplies data and operator roles. A "Finalize Procedure Information" dialog box may then appear, showing the Supplies tab. (For more information about this dialog box (not shown), see the "Finalize Procedure" descriptions (FIGS. 6C-6I, below).

[0162] The operator may also optionally select a procedure in the list and then click the Status button 509 to view more detailed information about the procedure. A Procedure Status dialog box 521 (see FIG. 5B) may then appear. (Optionally, the operator may double-click the selected procedure in the list to view this Procedure Status dialog box 521.) This dialog box 521 preferably shows the procedure time (time remaining, total time, and estimated end time) and the current collection status for each of the three blood product types (platelets, plasma, and RBCs) which may be in the process of being collected as part of a procedure.

[0163] Several alternative conditions and/or sub-procedures may be available in Procedure monitoring. For example, when an alarm, warning or alert condition occurs within an active separation and collection procedure, the system may change the icon next to the procedure description in the Monitor Procedure task window 501 to an "alarm" icon (not shown). The operator can view the alarm description (preferably uploaded automatically to central system 140 from the apheresis system 10 generated by the run data for the procedure) by selecting the procedure from the procedure list in the Monitor Procedure task window 501 procedures list 504, clicking the Procedure Information button 507, and then clicking a Procedure Log tab in the Finalize Procedure Information dialog box (see similar description in FIGS. 6C-6I, below). However, the alarm cannot be resolved in the preferred embodiment directly within the central system 140. The alarm must then be resolved at the machine 10. Once this alarm (and any other alarms on the machine) have been resolved at the machine 10, the central system 140 may change the icon next to the corresponding procedure description back to an "active procedure" icon such as icon 502, for example, as opposed to an inactive icon 503.

[0164] At any time, a procedure may no longer meet the active or pending criteria. An update to the visit status table in the central database 142 may cause a procedure that was previously displayed in the Monitor Procedure list on screen 501 of procedures to be removed from the list. Only procedures that have a status of active or pending are preferably displayed in the procedure list. If a procedure previously was active or pending, but no longer meets that criteria the next time central system 140 scans the visit status table, the procedure is no longer displayed in the Monitor Procedure task window 501.

[0165] At any point in monitoring procedures using screen 501, an operator may sort procedures in procedure list. In particular, the operator may click one of the column headings in the procedure list to sort the procedures using different criteria. Procedures may preferably be sorted by

one of the following: Machine ID, Status, Donor Name (first name, last name), Procedure, or Time Remaining. The first time the column heading is clicked, the procedures are sorted in ascending alphanumeric order. Each subsequent click of the column heading results in a display of the elements in the opposite alphanumeric order (ascending or descending).

[0166] As a usual last step in the overall blood component separation and collection process using a central system 140, the record finalization and reporting function of the computer/database system 140 will now be briefly introduced. First, the computer/database system 140 is preferably capable of capturing a great deal of optional information from the apheresis system 10 as well as from manual entry. This end-of-run information may then be used in generating a multitude of optional reports in addition to standard run records, both of which optionally being formattable as desired by the operator (see FIGS. 6K, 6L and 6M, described below). Further, various types of data can be sorted and measured relative to each other as desired as well. For example, the time period of the entire collection procedure can be reported relative to the numbers and/or quantities of the products collected (volumes or contents). Or, certain quality measures may be reported against either or any of the other data collected by the computer/database system 140. In addition, certain data may be manipulated, edited or amended, or comments added thereto after a collection procedure. For example, certain additional information may be added such as information about the type of tubing set used or post procedure laboratory values. Nevertheless, the data generated by the apheresis machine 10, itself, very preferably would not be capable of being edited or changed in any way. As above, more details of the overall reporting functionalities will now be set forth.

[0167] The present invention allows operators to search for and select any procedure record in the central database 142, whether the procedure record is opened (as for active and pending procedures) or closed (as for finalized procedures). As shown, for example by screen 601 in FIG. 6A, operators can search for procedure records based on donor ID, unit number, or a range of dates. Once the desired procedure record has been found, the operator can access the procedure record to do one of the following: View and/or enter finalization data (see the "Finalize Procedure Record" sub-procedure described below); or, View and/or enter lab results data (see the "Lab Results Entry/Edit" description below; FIG. 6J)

[0168] The Basic Flow of this sub-procedure case follows the scenario that the operator preferably searches by either donor ID or unit number, and that the operator wants to view/enter finalization data for the procedure. The operator preferably double-clicks the Select Procedure task icon 211 in the main task bar 205 (FIGS. 2A and 6A), or, alternatively, the operator may select the "Select Procedure" element (not shown) from the Tasks menu 216 (FIG. 2A). The operator may then search the central procedure record database 142 for the desired procedure record(s), either by donor ID (see field 602) or unit number (field 603). Searching by a range of dates (see fields 604) is another preferred alternative. The operator clicks the desired radio button, which clears any information which may be currently shown in other selection option fields, and the operator then enters a full or partial entry of the donor ID or unit number or dates

in the appropriate box. Logical and/or boolean-type searches are also preferably available. Alternatively, the operator may use the barcode reader (not shown) to enter the donor ID or unit number. For date searching, the operator may enter a starting date in the From box, and enter an ending date in the To box. Either date can be typed in the text box or selected using a pop-up calendar (see calendar 611 in FIG. 6B).

[0169] The operator may then click the Search button 610 or press the Enter key (on the keyboard, if used). The central system 140 then searches the central database 142 and displays all possible matching procedure records in the Search Results box 612. The search finds both open and closed procedure records. In date searching, the Search Results box displays all procedures that were performed within the specified date range.

[0170] The operator may then click the desired procedure record in the Search Results box 612, and then click the Procedure Information button 614 (shown grayed-out in FIGS. 6A and 6B, since a record is not yet selected there, i.e., is not yet highlighted. A Finalize Procedure Information dialog box 621, which may also be known as a Procedure Data Entry Edit box 621 (see FIGS. 6C-6I) then appears (optional double-clicking of the procedure entry in the Search Results box 612 may also display the Finalize Procedure Information dialog box 621), here showing a Supplies tab 631. (For more information about this dialog box, see the "Finalize Procedure" sub-procedure described below.)

[0171] Note, alternative search steps may also be performed. For example, if the operator clicks the Search button 610 with no search criteria given, then the Search Results box 612 preferably displays all procedure records in the central database 142. Alternatively, the correct procedure record may not be found, in which case the operator may then perform a new search by entering new search criteria.

[0172] Also, the operator may sort procedure records in Search Result box 612 by clicking one of the column headings in the Search Results box 612. This will sort the procedure records using different criteria. Procedure records may preferably be sorted by one of the following: Unit Number, Date, Donor ID, or Donor Name (first name, last name). The first time the column heading is clicked, the procedure records are sorted in ascending alpha-numeric order. Each subsequent click of a column heading results in presentation of the records in the opposite alphanumeric order (ascending or descending). The operator may also view a Lab Results Entry/Edit Dialog box (see box 701; FIG. 6J) by clicking the desired procedure record in the Search Results box 612, and then clicking the Lab button 616 to view the Lab Results Entry/Edit dialog box 701 (FIG. 6J).

[0173] The operator may preferably access the Finalize Procedure Information dialog box 621 for a particular procedure using one of two methods, the Monitor Procedure sub-procedure described above (see FIGS. 5A-5B), and/or the Select Procedure sub-procedure (FIG. 6A). The operator can access the Finalize Procedure Information dialog box 621 via the Select Procedure task window 601 (see FIGS. 6A and/or 6B), preferably if the following is true; the procedure will be run, is currently running, or has been run under control of the central system 140. Note that while using Select Procedure, the operator can preferably access the

Finalize Procedure Information dialog box 621 regardless of whether the procedure record is opened or closed (this is in contrast to Monitor Procedure; the procedure record must preferably be in open status in order to access it from the Monitor Procedure task window 501). In addition, once the procedure has been completed on the apheresis machine 10, the operator may use the Select Procedure task window 601 to access a Lab Results Entry/Edit dialog box 701 (FIG. 6J), allowing the operator to view/enter lab product results.

[0174] Moreover, the operator can preferably access the Finalize Procedure Information dialog box 621 any time after the Prepare Procedure Wizard (see description of FIGS. 3B-3F) has been completed for the donor/procedure. Thus, the operator may enter procedure information such as supplies and operator roles (see below) while the procedure is still running. However, even if all required data has been entered and saved in the procedure record, the procedure record is not considered closed until after the apheresis machine run has been completed (i.e., the central system 140 has detected a reboot or similar such signal from the apheresis machine 10). In addition, in order to update the status of a procedure record from open to closed, all required information must be present in the Finalize Procedure Information dialog box. Required information is preferably either or both dictated by the central system 140 (unit number, machine ID, donor ID, date), and determined by the System Administrator during system setup (required supplies, operator roles, etc.).

[0175] Once the central system 140 changes the status of a procedure record from open to closed, the central system 140 preferably removes the procedure from the Monitor Procedure list 504 (see FIG. 5A). After this point, the system 140 may require use of the Select Procedure task window 601 to revisit the procedure record. Note: a procedure is preferably also removed from the Monitor Procedure list 504 if a System Administrator forces record completion using button 511 in FIG. 5A (i.e., when the System Administrator determines that a record cannot or will not be closable in accordance with normal procedures as dictated herein).

[0176] To finalize a procedure, the operator will preferably select a procedure listed in either the Monitor Procedure window 501 (FIG. 5A) or the Select Procedure task window 601 (FIG. 6A), and then open the Finalize Procedure Information dialog box 621 (FIGS. 6C-6I). The procedure record for the selected procedure is then displayed in the Finalize Procedure Information dialog box 621, preferably in initial form with a Supplies tab 631 as shown in FIG. 6C by default.

[0177] In the top portion 629 of the Finalize Procedure Information dialog box 621, the operator confirms all preferably required and pre-populated procedure information, as follows: Unit Number; Machine ID; Procedure Date; Donor ID; Donor Name; and End Time. All of the above information is preferably non-editable, and is preferably downloaded from the central database 142 and/or the apheresis system 10 run data for this procedure.

[0178] On the Supplies tab 631 (FIG. 6C), the operator may enter procedure supplies data. The supplies data entries may include the following: an "X" box or column, and various columns which may include a Description, a Lot number, an Expiration date, and a Manufacturer column,

inter alia. In the "X" box/column, preferably the left-most column in the grid, the Administrator preferably defines which supplies entries are required, using an "X" in this cell for such required supply information. In the Description field, which is preferably non-editable as defined by an Administrator during setup, the Administrator preferably sets up supplies data by providing supplies descriptions and defining each supply as an optional or required entry. Each supply description the Administrator defines preferably appears in the Description column in the grid. The Lot number is preferably required if any supplies entry is a required entry. This can be typed into the box, or alternatively, the operator may use the barcode reader to enter this data automatically. The Expiration date is also preferably required if any supplies entry is a required entry. This also can be typed into the box, or alternatively, entered using a barcode reader to enter this data automatically. Similarly, the Manufacturer data is preferably required if any supplies entry is a required entry. Preferably a drop-down list, editable by selection only is used for entry here. Alternatively, the operator may use the barcode reader to enter this data automatically.

[0179] The operator may then optionally click the Operators tab 641 (see FIG. 6D) in the Procedure Data Entry/Edit screen 621 (also known as the Finalize Procedure Information screen 621; FIGS. 6C-6I) to access the operator role data entry area. Here, the operator may preferably enter information about operator roles. Each operator role entry may include the following: an "X" box or column; a Role column, and Operator ID and Name columns. The "X" box or column is again preferably the left-most column in the grid, with the Administrator having pre-defined an operator role entry as required such that an "X" appears in this cell for that role. The Role column is preferably non-editable, defined by the Administrator during system setup. The System Administrator preferably sets up operator roles data by providing operator role descriptions and defining each operator role as an optional or required entry. Each operator role description the Administrator defines appears in the Role column in the grid. The Operator ID and Name columns are preferably required if the operator role is a required entry. These may be drop-down lists, editable by selection only. When the operator selects an item in the Operator ID drop-down list, the corresponding Operator Name cell is preferably automatically populated with the operator's first and last names. Alternatively, an operator name can be typed in the box, but it reverts to match the currently-selected operator ID the next time the procedure record is displayed.

[0180] The operator may then optionally click the Donor Information tab 651 in screen 621 (FIG. 6E) to view the donor information for this procedure. The donor information is preferably supplied from the central donor database 142 and/or the blood bank information system, as well as information entered during the Prepare Procedure Wizard for this procedure. Once the central system 140 creates a procedure record for a procedure, the donor information becomes a part of the procedure record, providing a snapshot of this information on the date the procedure was run. This information is therefore preferably non-editable. The donor information preferably includes the following: Gender; Height; Weight; TBV (Total Blood Volume); Blood Type (if available); CMV and HLA status (if available); and Pre-procedure values for hematocrit and platelet count. In addition to the above

information, this tab 651 preferably also shows the post-procedure values for hematocrit and platelet count. This information is preferably provided from the apheresis system 10 run data for this procedure and thus, like the other information in this tab, these values are preferably non-editable.

[0181] The operator may then also optionally click the Record Status tab 661 in screen 621 (FIG. 6F) to view the current central system procedure record status. The status options preferably update automatically during the procedure run and procedure record entry. The options, which are preferably non-editable within this module, may include the Procedure Record, the Machine Release, the Visit Status and the Reason. The Procedure Record preferably remains Opened until all required information has been entered in the procedure record; at that point, the central system may update this option to Closed. A check box can be used to indicate whether the machine has been released for the next donor. The Visit Status preferably shows the current status of the donor's visit (for example, if the procedure is currently running, this box shows the same status that is shown in the Monitor Procedure task window 501 (FIG. 5A) for this procedure). The Reason field may preferably be used to indicate whether and/or if the donor was removed from the Donor Assignment Queue 406 in the Assign Machine task window 401 (FIG. 4A) for any reason (incomplete procedure, dismissed at the apheresis system 10, etc.); the reason being displayed in this box.

[0182] The operator may then optionally click the Procedure Log tab 671 (see FIG. 6G) to view the procedure name and the procedure log (an event log of all machine alerts, alarms, warnings, and operator adjustments entered throughout the procedure). Procedure comments that have been entered by a system operator may be intermixed (according to timestamp) with the other information in this scrollable region. This information is preferably variable for active donations and remains at the final status display for pending and finalized procedures. The information is preferably non-editable and is preferably supplied by the apheresis machine 10 run data and by the operator entering procedure comments either in this dialog box 671 or via the Monitor Procedure task window 501 (FIG. 5A). The operator may optionally click the Comment button to enter a comment in the procedure record for that procedure. An Enter Procedure Comment dialog box (not shown) may be made to appear. The operator can select a comment from the pre-configured comment list (preferably created by the Administrator) and/or enter a free-form text comment entry. If the operator clicks the OK option, the Finalize Procedure Information dialog box 621, Procedure Log tab 671 is redisplayed, showing the date and time the comment was created, as well as the user ID for the user who was logged on when the comment was created. If the operator clicks Cancel, the Finalize Procedure Information dialog box 621, Procedure Log tab 671 is redisplayed, but the comment is not included in the procedure record.

[0183] The operator may then optionally click the Run Summary Tab 681 (FIG. 6H) to view the machine-estimated product volume information. This information is preferably provided by the apheresis machine 10 after the run is complete. Until the procedure is completed, all of the fields in this tab are blank. The information would then be non-editable and defaulted from the procedure run data (machine

run summary). This information preferably includes the following: the estimated volume for platelet, plasma and RBC products; the AC volume in platelet, plasma and RBC products; the estimated yield for platelet products; the total AC volume used; the AC administered to the donor during the procedure; the total blood volume processed; and Summary remarks, preferably including one or more of the following: a reminder to label LRS platelet product as having less than 1×10^6 white blood cells (if so leukoreduced, as on the Trima® system 10; a reminder to count the product; a reminder to verify platelet yield; a reminder to verify platelet volume; a reminder to determine whether platelet concentration is out of range; a reminder to verify plasma volume; and/or a reminder to verify RBC product.

[0184] The operator may then optionally click the Blood Loss Tab 691 (FIG. 6I) to view blood loss entries. Blood loss information preferably includes the Product, the Tubing Set Residual, the Blood Sample and an Other column. A check box for Rinseback Completion is also provided. In more detail, the Product column shows product volume for plasma and RBCs. This information is preferably downloaded from the apheresis system 10 run data for this procedure, and is preferably non-editable. The information is determined based on the procedure that was run and the donor's hematocrit. Until the procedure is completed, these fields are blank. The Tubing Set Residual preferably shows the volume of plasma and RBCs remaining in the tubing set. This information is also preferably downloaded from the apheresis system run data for this procedure, and is preferably non-editable. During the procedure, this information is determined based on the collection status, the tubing set type, the procedure that is being run, and the donor's hematocrit. When the procedure is completed, this information is determined based on all of the above, as well as whether or not rinseback was completed for the procedure. The Blood Sample column presents the volume of blood, entered by operator for plasma and/or RBCs, according to the facility's SOPs. The default value if, used, is preferably specified by the Administrator. The Other column includes any Other volume of blood (for example, estimated volume of a spill), entered by operator for plasma and/or RBCs, according to the facility's SOPs. The Donor Completed Rinseback check box is checked if rinseback was completed for the procedure. Until the procedure is completed, this box remains unchecked. This information is also preferably downloaded from the apheresis system run data for this procedure, and is preferably non-editable.

[0185] After entering and/or confirming the above data (particularly as may be required by the SOP's of a particular blood center), the operator may then click the "OK" button 622 (FIGS. 6C-6I) to save the record. The central system 140 saves the procedure record. If all the required information has been entered, the central system 140 updates the status of the record to be closed. The central system 140 may then also close the Finalize Procedure Information dialog box 621 and redisplay either the Monitor Procedure task window 501 (FIG. 5A) or the Select Procedure task window 601 (FIG. 6A), depending on the method the operator originally used to open the Finalize Procedure Information dialog box 621.

[0186] Alternatively, the Operator may click the Apply button 624, at any point while the Finalize Procedure Information dialog box 621 is displayed to save the data in

the procedure record up to that point, without closing the dialog box 621. The central system 140 saves the procedure record and, if all the required information has been entered, the system 140 updates the record's status to closed. Similarly, at any point while the Finalize Procedure Information dialog box 621 is displayed, the operator may click the Cancel button to cancel the current entry session. The central system 140 may then discard all unsaved changes in the procedure record, and close the Finalize Procedure Information dialog box 621 and redisplay either the Monitor Procedure task window 501 or the Select Procedure task window 601, depending on the method the operator used to open the Finalize Procedure Information dialog box 621.

[0187] Various alternative actions are also available. For example, the Operator may view a record for a procedure which has not yet begun. The central system 140 creates a procedure record as soon as the operator completes the Prepare Procedure Wizard for a procedure (see FIGS. 3B-3E). However, the procedure does not appear in the Monitor Procedure task window until the donor and procedure information is downloaded to the assigned apheresis system 10. Prior to that time, if the operator wants to view the procedure record, he/she can search for the procedure record using the Select Procedure task window 601. The operator may also view and/or edit information in the Finalize Procedure Information dialog box 621, as described here; i.e., at any point in the overall process, however, in most instances, doing so at before a process has begun or during the process would be premature.

[0188] However, Lab data entry/edit may also be performed from screen 601 (as introduced above) at any time in the overall process; generally after such data has been processed and returned from the Laboratory. Again, the Lab Data Entry/Edit screen 701 (FIG. 6J) is preferably accessed by selecting the Lab button 611 in screen 601 (FIG. 6A). Then, lab information may be entered/edited in screen 701 according to the product types (see the three tabs for Platelet Products, Plasma Products and Red Blood Cell Products). Then, Lab data entry/editing may be performed according to the information on hand. For example, Collected Product information can be entered/edited (although this information may be downloaded from the apheresis machine 10, and thus may be made non-enterable/non-editable, here); Residual Count information can be edited/edited (as may be applicable); and Split Product information may be entered/edited (Split ID numbers; concentrations, bag weights, volumes and/or yields, e.g.), here.

[0189] During use of the Select Procedure task window 601, the operator may click one of the column headings in a grid to sort the entries using different criteria. The first time the column heading is clicked, the entries are sorted in ascending alphanumeric order. Each subsequent click of the column heading results in the opposite alphanumeric order (ascending or descending).

[0190] Note, the Donor may be dismissed at the Machine 10 after the central system has initiated a record. In such a case, the central system 140 preferably automatically closes the procedure record if both of the following are true: The donor is assigned to an apheresis system, but then is dismissed using the apheresis system touch-screen display 199 before the procedure is begun; and, the operator does not assign the donor to a different machine 10, but instead

removes the donor from the Donor Assignment Queue 406 in the Assign Machine task window 401 (See FIG. 4A). For more information, see the following alternative actions described relative to the "Assign Machine" sub-procedure relative to FIGS. 4A and 4B.

[0191] The central system may also detect an Incomplete Run, in which case, the system 140 preferably automatically closes the procedure record if both of the following are true: the donor is disconnected from the apheresis system 10 and the operator indicates on the machine that the run is incomplete, and the operator has completed all information necessary to finalize the procedure record. If the operator has not yet completed all information necessary to finalize the procedure record, the procedure record remains opened until such information has been entered, as described, above.

[0192] Note, throughout the descriptions of preferred options above, there are set forth a plurality of described instances of data/information preferably being communicated to and from the central system 140 from and to the apheresis system(s) 10. Nevertheless, it is understood that not all of these particular types of data or information may be used or captured or communicated by many available blood processing systems. Thus, it should be understood that all such instances in the above description are intended as the preferred embodiment, and that lesser direct communications and mere manual data transfer from and to a central system 140 and associated blood processing systems 10 are also intended within the scope of the present invention. Thus, for example, data may be manipulated and/or optimized on/in a central system 140, and the results of which may not be readily transferred to a blood processing system 10 (see perhaps systems 10B and/or 10C as shown in FIG. 1B, e.g.), and therefore the resulting manipulated and/or optimized data or information may have to be operator entered into such a system 10 for use thereby. Similarly, the results of the processing/collection procedure performed by a lesser compatible system (see again, perhaps systems 10B and/or 10C, e.g.) may not be automatically communicable to the central system 140, but may be operator transferred (i.e., manually entered) upon procedure completion. Instances of preferably non-editable fields or data, as set forth above, would thus not be applicable here. Rather, such data fields would indeed be editable/enterable depending upon which type of blood processing system 10 were being used. A further similar process for data handling may be performed for whole blood collection systems (see e.g., the whole blood representation 10D in FIG. 1B), wherein a data communicating machine is often not used (at least not in the initial collection process; a needle connected to a receptacle/bag by a tube may be the collection device 10D). However, data/information may still be captured by manual data entry throughout the process, for example, from initial Reception and Screening through to Collection completion. Moreover, subsequent (or chair-side, or bed-side) processing may even be performed such as to separate the collected whole blood into components which may be desirably tracked in a central system 140. The data would rather only be manually entered, or perhaps even certain subsequent (or chair-side, or bed-side) processing machines may have data communication abilities so as to communicate with a central system 140. The quantity and/or quality of data would then only differ as to the type of procedure performed (e.g., whole blood separated into which components).

[0193] Lastly, if the operator desires to view and/or print an End-of-Run report when the procedure is complete, he/she may do so using the Reports feature of the Everest software (see generally FIGS. 6K, 6L and 6M, for example). Various pre-defined and/or system administrator defined reports are preferably generatable about donors, procedures and collected blood products, inter alia. The reports command may be an icon in the icon task bar 205 (though not shown as such here), or may be accessible through the Tasks menu 216 (see FIG. 2A, e.g.), inter alia. A list of previously configured reports may then be made to appear as for example is shown in dialog box 711 of FIG. 6K. Upon selection of a report from the list in box 711, a report generating dialog box such as box 721 (FIG. 6L) may then be made to appear. After entry of the prompted-for information, a report may then be generated. An example report is shown in the report previewer screen 731 (FIG. 6M). The presently preferred report generator is based on the Oracle® Reports platform which is a readily-available software application (from the Oracle Corporation, Redwood Shores, Calif.). Thus, data from the central may be transferred to such a Report generating platform to create reports of any desirable format in fashions known and understood by those skilled with Oracle® Reports or like software applications.

[0194] As mentioned throughout, an important element of the overall system 140 is the communication subsystem 146 which provides communication between and/or among the various other devices/elements. As described above, subsystem 146 may involve hardware or cable connections between the various elements; and/or it may involve other devices and/or software. A further communication alternative with the computer/database 140 may generally involve the internet. As is known in the art, the internet provides a "common language" through which multiple different systems can communicate without requiring special tailoring of each system. For instance, various protocols have been established to facilitate data communication on what has become known as the internet. In particular, the TCP-IP (Transmission Control Protocol—Internet Protocol) is an internet protocol structure which was developed in a 1973 Department of Defense research project designed to link a "network of lowest bidders"; now in wide commercial usage since about 1988. In particular, the TCP ensures that the information goes to its destination correctly; verifies the correct delivery of data from client to server; and provides a common way of sharing information among different types of systems (PC, MAC, SUN workstation, etc.). Further, the IP also ensures the information goes to the right location; moves packets of information from node to node; and provides unique IP addresses assigned by InterNIC (NSF, AT&T, & Network Solutions, inter alia.). The Internet then provides a web of information which can be accessed through a single interface (web browser). The internet can also provide a communication medium between a computer/database system 140 and various other computer information systems such as those shown in FIG. 1B; and ostensibly provide communication protocols to or with the apheresis machines 10 as well.

[0195] As an example, as inventory is withdrawn or replenished within the hospital or blood bank, this information can be recorded via bar code. By connecting the information to the hospital information system (HIS) and on through to bloodaccess.com, or a like internet connection

address, a blood donation center can then access and monitor local inventory levels. When one hospital needs a stat or immediate order for a given blood component, the blood center may then locate and arrange transfer of the units from one center or one hospital to another. The blood center can then replenish the units taken from the hospital within a short period of time (such as 24 hours) using flexible collection through automation. Moreover, this is not merely an inventory tool, it may also be tailored to fill specific needs such as in the "dosing" model introduced herein.

[0196] Similarly also, donor recruitment and/or eligibility and/or qualification can be run by a centralized system to determine which donors may be able to provide certain products at a certain time. The data may be obtained by data input as above, or with data already existing in the memory 142 and/or as may be obtained by communication with a discrete information system. Most preferably, these procedures could be performed without the specific potential donor present to predict what the donor could yield, and then if a desirable product is predicted (i.e., the potential donor is eligible or qualified to give the desired product(s)), the potential donor could then be contacted to recruit them to undergo the procedure. In this fashion, a blood center could better tailor its blood and blood component supply to better match demand.

[0197] By way of background and provision of a detailed application of the present invention, a description of the blood apheresis process and associated machinery will now be set forth. Various embodiments of blood component collection assemblies may incorporate principles of the present invention. However, as noted above on-line techniques have been determined to be quite effective and thus the present invention is being described with reference to such techniques. One embodiment of an on-line technique and attendant apparatus which may be incorporated into the blood component collection system 2 of FIG. 1A is illustrated in FIG. 7A. An on-line technique herein refers to the use of a blood processing device which is controlled by parameters entered directly therein and calculated or manipulated thereby to achieve all necessary control parameters. Off-line techniques refer to the use of data entry and/or data manipulation performed by devices not resident on or within the particular blood processing device; though which are preferably disposed in data communication therewith.

[0198] The blood component collection assembly 10' of FIG. 7A utilizes an on-line technique in that a donor 14 (e.g., the whole blood source) is directly integrated with the system 10' by fluid interconnection with the blood component collection device 18. This particular on-line technique is more particularly referred to as a dual needle configuration since there are two fluid interconnections between the donor 14 and the blood component collection device 18.

[0199] The donor 14 is fluidly connected to the blood component collection device 18 by an inlet line 22 and appropriate needle assembly (not shown). Whole blood from the donor 14 is thus continuously provided to the blood component collection device 18 through the inlet line 22 for separation of the desired blood component(s) therefrom, utilizing an inlet pump 26 (e.g., a peristaltic pump) to maintain this flow if desired/required. Prior to the blood of the donor 14 entering the blood component collection device 18, anticoagulant from an anticoagulant ("AC") container 30

may be provided to the whole blood, utilizing an AC pump 32 (e.g., a peristaltic pump) to maintain this particular flow if desired/required. Consequently, the inlet flow to the blood component collection device 18 typically includes both a flow of whole blood from the donor 14 and a flow of anticoagulant from the AC container 30.

[0200] The blood component collection device 18 separates the whole blood provided on-line by the donor 14 into three primary constituents, namely platelets, a combination of red and white blood cells ("RBC/WBC"), and plasma. The platelets collected from the blood component device 18 are directed through a platelet collect line(s) 34 to one or more platelet collect bags 38 via a collect pump 36. The plasma and RBC/WBC are provided back to the donor 14 through a plasma line 42 and RBC/WBC line 46, respectively, both of which are interconnected with a second needle assembly (not shown) on the donor 14 via a donor return line 50. The plasma line 42 includes a plasma pump 40 (e.g., a peristaltic pump) to maintain the flow of plasma if desired/required. Although plasma may be provided back to the donor 14 in the above manner, it may be desirable to collect the separated plasma in some cases. In this regard, a plasma collect bag 54 may be provided and interconnected with the plasma line 42 (interconnection shown in phantom). In this case, appropriate valving 56 may be incorporated in the plasma line 42.

[0201] The blood component separation assembly 10" of FIG. 7B is similar to that of the dual needle configuration of FIG. 7A except that a single needle assembly (not shown) integrates the donor 14 within the blood component collection assembly 10". Consequently, similar components are similarly identified where appropriate. With regard to the single needle configuration of FIG. 7B, whole blood of the donor 14 initially flows through a donor access line 62 and into an inlet line 66 which is fluidly connected with the blood component collection device 18 such that the platelets are separated and collected in the above-described manner. The plasma and RBC from the blood component collection device 18 flow through the plasma and RBC/WBC lines 42, 46, respectively, both of which are fluidly interconnected with a return flow controller 74. As above, however, the plasma may alternatively be directed to a plasma collect bag 54. In the event that plasma is not collected, the RBC/WBC and plasma are provided back to the donor 14 through the return flow controller 74 via a donor return line 70 which is interconnected with the donor access line 62. As can be appreciated, since only a single line is directly connected to the donor 14, namely the donor access line 62, blood is either being removed from or provided back to the donor 14 such that the procedure is effectively two-step versus continuous in relation to the donor 14.

[0202] An exemplary blood component collection device 18 which may be used in the blood component collection assembly 10 is more particularly illustrated in FIGS. 8A-8B. This and like devices 18 are the subject of various U.S. Patents, see particularly U.S. Pat. No. 4,387,848 to Kellogg et al., entitled Centrifuge Assembly, issued Jun. 14, 1983, and U.S. Pat. No. 4,708,712 to Mulzet, entitled Continuous-loop Centrifugal Separator, issued Nov. 24, 1987; inter alia, the disclosures of which are incorporated by reference in entirety herein. Such devices 18 are also commercially

available from the assignee of the present application as such may be incorporated in the COBE Spectra® and/or Trima® apheresis systems.

[0203] Referring to FIGS. 8A-8B, the blood component collection device 18 utilizes a processing channel 80 to provide the desired disposable extracorporeal circuit. The channel 80 is positioned preferably within a groove formed directly or indirectly in a centrifuge rotor (not shown) (e.g., a separate filler may receive the channel 80 and be attached to the centrifuge rotor), and is illustrated in the two-stage shape which it assumes during processing (i.e., during flow of blood therethrough). Although a two-stage channel 80 is shown and described further herein, the present invention is not so limited; rather, the present invention may be used also with single-stage and/or any other centrifugal configuration as well as with non-centrifugal separation machines or devices.

[0204] As shown and described herein, the two-stage processing channel 80 generally includes a first stage 84 for collectively separating red blood cells ("RBC") and white blood cells ("WBC") from platelet-rich plasma, a second stage 92 for thereafter separating platelets from the platelet-rich plasma, a transition portion 88 defining a separation between the first stage 84 and second stage 92, and a control chamber 124 for maintaining a proper interface between the first stage 84 and second stage 92, namely the position of the interface between the RBC/WBC and platelet-rich plasma within the transition portion 88.

[0205] The first stage 84 extends from one end of the control chamber 124 along an arcuate path generally inwardly, toward the axis 132 about which the processing channel 80 rotates via the centrifuge rotor, until terminating at the transition portion 88. Specifically, the end of the first stage 84 adjacent the control chamber 124 is positioned at a greater radial distance from the axis 132 than the end of the first stage 84 adjacent the transition portion 88. An inlet tube 96 is fluidly connected with the first stage 84 between its two ends to introduce whole blood into the processing channel 80 and a RBC/WBC tube 100 is provided in the control chamber 124 for removing the separated RBC/WBC from the channel 80. Both the inlet tube 96 and RBC/WBC tube 100 extend externally of the rotatable device 18 for interconnection with the donor 14 and/or collection bags 38, 54.

[0206] As RBC/WBC sediment against the outer wall in the first stage 84 during rotation of the centrifuge rotor they are directed and counterflow toward the RBC/WBC tube 100 for removal from the channel 80 due to the increased centrifugal forces at the RBC/WBC tube 100 in comparison with the transition portion 88. That is, since the first stage 84 extends along an arcuate path generally outwardly away from the axis 132 proceeding from the transition portion 88 to the control chamber 124, the centrifugal force differential along the first stage 84 establishes the described counterflow of the separated RBC/WBC. Moreover, the transition portion 88 also assists in providing for this counterflow since it extends along an arcuate path generally inwardly toward the axis 132 proceeding from the first stage 84 to the second stage 92.

[0207] The platelet-rich plasma, which has a lower density than the RBC and WBC, flows beyond the transition portion 88 from the first stage 84 into the second stage 92 for further processing, while the RBC/WBC are directed back toward

the RBC/WBC tube 100 in the above-described manner. The second stage 92 initiates at the radially inwardmost part of the transition portion 88 and extends along an arcuate path generally outwardly away from the axis 132 to a platelet collection chamber 104. Platelets are removed from the processing channel 80 at the platelet collection chamber 104 by a platelet tube 108 which interfaces with the outer wall of the processing channel 80 at the platelet collection chamber 104. Thereafter, the second stage 92 extends along an arcuate path generally inwardly toward the axis 132 until terminating at the plasma tube 112. Both the platelet tube 108 and plasma tube 112 extend externally of the rotatable device 18 for interconnection with the platelet collect bag(s) 38 and donor 14/plasma collect bag(s) 54, respectively.

[0208] Platelets which do not separate from the plasma in the initial portion of the second stage 92 between the transition portion 88 and platelet collection chamber 104 are separated in the portion of the second stage 92 between the platelet collection chamber 104 and the plasma tube 112. These platelets will flow back towards the platelet collection chamber 104 in the opposite direction of the flow of platelet-rich plasma/platelet-poor plasma through the second stage 92 due to the configuration of this portion of the second stage 92. That is, the platelet collection chamber 104 assumes the radially outwardmost position in the second stage 92 such that all platelets, regardless of where separation occurs in the second stage 92, flow towards the platelet collection chamber 104 for removal from the channel 80.

[0209] Platelet-poor plasma exits the second stage 92 and flows out through the plasma tube 112 which interfaces with the inner wall of the processing channel 80 and/or continues to flow through the remaining portion of the processing channel 80 to the control chamber 124. Plasma which flows to the control chamber 124 exits the channel through the control tube 114 which joins with the RBC/WBC tube 100 into a single outlet tube 120. The positionings and diameters of the RBC/WBC tube 100 and control tube 114 and the joiner of such into the common outlet tube 120 regulate the position of the RBC/WBC-platelet-rich plasma interface within the transition portion 88 using conservation of mass principles.

[0210] As noted above, each blood component collection device 18 may include a prediction model appropriately interfaced with the operator input module 16 and/or disposed on or within the manipulation device 144 or in an associated memory device 142 as shown in FIGS. 1A-1D any and/or all of which may be used to configure the prediction model and/or to allow operator input of various parameters to be used by the prediction model for predicting a yield of a particular blood component to be collected before a collection procedure is initiated using a compilation of algorithms. The preferred prediction model and the optimization algorithms which are associated with the present invention are described in detail in U.S. Pat. Nos. 5,496,265; 5,658,240; 5,712,798; and 5,970,423; inter alia, all of which being commonly assigned to the assignee of the present invention, the disclosures of which being incorporated herein in their entireties as if fully set forth here by this reference thereto. The algorithms and disclosures thereof will thus be only briefly described herein.

[0211] The prediction model is typically configured by the site (e.g., the blood bank/center) for a particular blood processing or component collection procedure (e.g., single or dual needle) used by the site. Both single-needle and double needle procedures as shown in FIGS. 7A and 7B

will be used in the following general description, particularly in relation to a platelet-collecting procedure (although of course, any collection procedure can be understood as being substitutable herein). In this regard, an AC infusion rate (i.e., the rate at which anticoagulant is provided to the donor 14 per the blood volume of the donor 14) and the AC ratio (i.e., the collective flow of AC and blood through the inlet line 22 in relation to the flow of AC through the line 22) must be specified (through configuration or modified input as will be discussed below). Moreover, in the event that plasma is to be collected into the plasma collect bag 54 in the collection procedure, the maximum amount of plasma which should be collected considering the medical and physical characteristics of the donor 14 must also be provided.

[0212] And, as described in the above-mentioned patents, there are two alternatives for establishing the plasma volume limit. These will not therefore be described further here.

[0213] Further information is required by the prediction model prior to performing its yield prediction function. For instance, the total procedure time is typically input by the operator or pre-configured by the site (e.g., the blood bank/center). Moreover, the total procedure time may be affected by whether a stepdown option is utilized for the blood component collection device 18 so as to enhance separation of the various blood components. When this stepdown option is selected, the angular velocity of the blood component collection device 18 is incrementally reduced during the platelet-collection procedure. For instance, the stepdown option could provide for angular velocities for the device 18 of 2400, 2200, and 2000 RPM, each of which would be for a specified duration.

[0214] Based upon the foregoing, the configuration of the prediction model in relation to the blood component separation assembly 10' and associated protocol in effect standardizes site protocol for purposes of "normal" operations. However, for a particular donor 14 it may be desirable to alter the "configuration" for one processing run. Consequently, the prediction model may utilize a procedure in which certain parameters utilized in the following equations may be adjusted on a one-at-a-time basis. Such is referred to as modified input data and the associated parameters are procedure time, inlet flow rate to the device 18, AC ratio option, the desired platelet collect volume, the desired platelet collect concentration, and the desired source plasma volume to be collected. Moreover, other parameters such as AC infusion rate, stepdown option (yes or no), needle option (single or double), and high flow option (yes or no) may also be entered as modified input data by an operator.

[0215] Having configured the prediction model in the above-described manner, the following additional information is provided and is utilized in the various calculations of exemplary Equations 1-22 presented below: (1) needle option, namely whether the procedure is dual needle (FIG. 7A) or single needle (FIG. 7B); (2) run identification number for purposes of associating the data/output generated by the various equations with a particular donor 14 and processing run; (3) the gender of the donor 14; (4) the height of the donor 14; (5) the weight of the donor 14; (6) the total blood volume as calculated in Eq. 10 below; (7) the hematocrit of the donor 14, either based upon an initial estimation and thereafter updated based upon analysis of the donor's 14 blood sample (e.g., by a cell counter) or input directly from

such an analysis; (8) the platelet pre-count, either based upon an initial estimation and thereafter updated based upon analysis of the donor's 14 blood sample (e.g., cell counter) or input directly from such an analysis; and (9) whether plasma collection is desired in conjunction with the platelet collection.

[0216] Based upon the above initial configuration and subsequent data input (except when entered as modified input data), the following output is generated by the prediction model: (1) platelet yield; (2) inlet flow rate; (3) AC ratio; (4) procedure time; (5) platelet collect volume; (6) platelet collect concentration; (7) source plasma volume; (8) AC in the platelet and plasma collect bags 38, 54; (9) platelet post-count; (10) AC infusion rate; and (11) output approval. This information is utilized at least in part in the following equations to generate, inter alia, the predicted platelet yield value of the collected platelets for the case of the dual needle procedure of FIG. 7A and also for the case of the single needle procedure of FIG. 7B. The differences between those procedures with regard to the prediction model are identified herein. As will be appreciated, some of the equations are utilized in the calculation of the predicted platelet yield, whereas other equations are used to generate additional information for output and informational purposes. The variables or parameters and the units associated therewith of the equations are presented after the equations in the Variables Index.

[0217] Platelet Yield:

$$Y=1 \times 10^6 C_{PR} V_B F_Y [1 - \exp(-E_c(f_{BP}-0.12))] \quad (\text{Eq. 1})$$

[0218] where:

$$f_{BP}=(Q_{IN}t_E+50)(1-1/R)/V_B \quad (\text{Eq. 2})$$

[0219] and where:

$$Q_{IN}=RQ_{AC}=0.001/IV_{BP} \leq 150 \quad (\text{Eq. 3})$$

[0220] Alternatively, the platelet yield may be expressed as:

$$Y=1 \times 10^6 C_{PR} V_B F_Y [1 - \exp(-E_c(0.001/(R-1)P_{t_E}+50(1-1/R)/V_B-0.12))] \geq 0 \quad (\text{Eq. 4})$$

[0221] Platelet Collection Efficiency:

$$E_c=C_1-C_2 \exp[9.91(1-1/R)H]Q_{INA} \geq 0 \quad (\text{Eq. 5})$$

[0222] where the constant C_1 is defined as follows:

[0223] $C_1=0.803$ —dual needle, without stepdown

[0224] $C_1=0.840$ —dual needle, with stepdown

[0225] where the constant C_2 is defined as follows:

[0226] $C_2=4.08 \times 10^{-5}$ —dual needle, without stepdown

[0227] —dual needle, with stepdown

[0228] and where:

$$Q_{INA}=Q_{IN}(t_E/t_P) \quad (\text{Eq. 6})$$

[0229] In Eq. 6, t_P may be provided as configuration data or modified data as provided above, or alternatively may be derived from the solution of Eq. 4 for t_E .

[0230] Effective Procedure Time:

$$t_E=t_P \quad Q_{IN} \leq 45=t_P-500(1/45-1/Q_{IN}), \quad Q_{IN} > 45 \quad (\text{Eq. 7})$$

[0231] Only high-flow protocol is used for $Q_{IN} > 45$.

[0232] AC Infusion Rate Constant:

$$I=1000Q_{IN}/(PRV_B) \quad (\text{Eq. 8})$$

[0233] Alternatively to the use of Eq. 8 for the derivation of the AC infusion rate constant I , such may be provided as configuration or modified input data pursuant to the above.

[0234] AC Ratio:

[0235] Initially, the AC ratio may be provided as configuration or modified input data pursuant to the above. In configuration, it is defined as follows:

$$R=1+2.51/H \text{ flow}=1.33(1+2.51/H) \quad \text{medium}=1.67(1+2.51/H) \text{ high} \quad (\text{Eq. 9})$$

[0236] Total Blood Volume:

$$V_B=604+0.006012 \quad L^3+14.6 \quad W \quad \text{ml (male)}=183+0.005835 \quad L^3+15.0 \quad W \quad \text{ml (female)} \quad (\text{Eq. 10})$$

[0237] Plasma Collect Factor:

[0238] AC infusion rate control maintains the AC flow to the donor as:

$$Q_{ACD}=0.001 \quad I \quad V_B \quad (\text{Eq. 11})$$

[0239] where the inlet flow associated with this is:

$$Q_{INO}=RQ_{ACD}=0.001 \quad IRV_B \quad (\text{Eq. 12})$$

[0240] Q_{IN} is proportional to the total AC flow, as given by Eq. 3, which includes the AC that flows to the platelet collect bag 38 and the plasma collect bag 54. P (Eq. 13) is the factor by which Q_{IN} is increased by collecting AC, relative to not collecting AC. That is,

$$P=Q_{IN}/Q_{INO}=(\text{average } Q_{AC})/Q_{ACD} \quad (\text{Eq. 13})$$

[0241] where:

$$\frac{P1+(f_{ACP}/Q_{ACD})}{Q_{INO}} \quad [V_C/(t_P-150/Q_{INO})+V_{SP}/(t_P-500/Q_{INO})] \quad (\text{Eq. 14})$$

[0242] and where:

$$f_{ACP}=[(R-1)(1-H)]^{-1} \quad (\text{Eq. 15})$$

[0243] Platelet Collect Volume:

$$V_C=1 \times 10^{-4} Y/[C_B(1+f_{ACP})] \quad (\text{Eq. 16})$$

[0244] Source Plasma Volume:

[0245] The four choices provided are as follows:

$$\left. \begin{aligned} V_{SP} &= 0 \\ &= V_{CON} - V_C \\ &= f_{SP} V_B - V_C \\ &= \text{specified as modified input} \end{aligned} \right\} \geq 0 \quad (\text{Eq. 17})$$

[0246] where:

$$V_{CON}=V_{CONL} \quad W < W_C=V_{CONH} \quad W \geq W_C \quad (\text{Eq. 18})$$

[0247] and where:

$$0.01 \leq f_{SP} \leq 0.15 \quad (\text{Eq. 19})$$

[0248] Donor Post-count:

$$C_{PO}=C_{PR} \exp[-E_c(0.001/(R-1)P_{t_E}+50(1-1/R)/V_B-0.12)] \leq C_{PR} \quad (\text{Eq. 20})$$

[0249] A warning is given if $C_{PO} < 100$.

[0250] Collect Volumes:

$$V_{CB}=V_C(1+f_{ACP}) \quad (\text{Eq. 21})$$

$$V_{SPB}=V_{SP}(1+f_{ACP}) \quad (\text{Eq. 22})$$

[0251] The primary equation to be solved for purposes of the yield prediction by the prediction model is Eq. 4. Consequently, Eqs. 1-3 and 5-22 are ancillary to Eq. 4

although they may be used to calculate other output data and/or information required by Eq. 4. With regard to the manner in which Eqs. 1-22 are solved, all the iteration loops are preferably based on the technique of successive approximation, in which each iteration is a repeat of the previous one, but using updated parameter values calculated in the previous iteration. This process continues until all the convergence criteria are met. The convergence criteria are that, on successive iterations, the variable difference is ≤ 1 for V_c , ≤ 0.2 for t_E , and ≤ 10 for C_B .

[0252] As noted above, the foregoing was based upon a dual needle configuration as illustrated in FIG. 7A. In the event that a single needle configuration such as that illustrated in FIG. 7B is utilized, the following Eq. 7' is used in place of Eq. 7 and the constants C_1 and C_2 for Eq. 5 are as follows:

$$\begin{aligned} C_1 &= 0.803 \\ C_2 &= 8.54 \times 10^{-5} \\ -t_E - t_P, Q_{DN} \leq 20 &= t_P - 215(1/20 - 1/Q_{DN}), Q_{DN} > 20 \end{aligned} \quad (\text{eq. 7})$$

Variables Index

[0253] Symbols for Equations:

[0254] C_1, C_2 =constants in platelet collection efficiency equations

[0255] C_B =platelet concentration in collect bag, expressed as 10^3 platelets/microliter

[0256] C_{PO} =donor post-count, expressed as 10^3 platelets/microliter

[0257] C_{PR} =donor pre-count, expressed as 10^3 platelets/microliter

[0258] EC =platelet collection efficiency

[0259] f_{ACP} =AC expressed as a fraction of pure plasma volume

[0260] f_{BP} =fraction of VB processed in platelet collection procedure

[0261] f_{SP} =VCON expressed as a fraction of VB

[0262] FY =user-specific (e.g., blood bank/center) yield calibration factor

[0263] H =hematocrit of donor or patient

[0264] I =AC infusion rate constant

[0265] L =donor or patient height, inches

[0266] P =plasma collect factor

[0267] QAC =AC flow, ml/min

[0268] $QACD$ =AC flow infused into donor for platelet collection procedures, ml/min

[0269] QIN =inlet flow, ml/min

[0270] $QINA$ =average inlet flow for platelet procedures, ml/min

[0271] $QINO=QACD$ =inlet flow associated with QACD, ml/min

[0272] AC =ratio

[0273] t_E =equivalent procedure time, min

[0274] t_P =procedure time, min

[0275] VB =total blood volume of donor or patient, ml

[0276] V =volume of pure plasma in platelet collect bag, ml

[0277] VCB =total volume in platelet collect bag, ml

[0278] $VCON$ =volume constraint for total pure plasma collected, ml

[0279] $VCONH$ =higher value of VCON, ml

[0280] $VCONL$ =lower value of VCON, ml

[0281] VSP =volume of pure plasma in source plasma bag, ml

[0282] $VSPB$ =total volume in source plasma bag, ml

[0283] W =donor or patient weight, lbs

[0284] WC =weight constraint associated with VCON, lb

[0285] Y =platelet yield, number of platelets.

[0286] As noted above, the computer/database assembly 140 associated with principles of the present invention interfaces with or at least provides information to one or more blood component collection assemblies 10 to provide a blood component collection system 2. That is, although there are definite advantages to having an interface between the computer/database assembly 140, and the blood component collection device 18, the optimization procedure may be performed at any location and input into the blood component collection device 18 in any manner. Since the general principles of the blood component collection assembly 10 were described with relation to the collection assemblies 10', 10" (FIGS. 7A and 7B) which included the blood component collection device 18 and its various features, the computer/database assembly 140 will be described in relation to such assemblies 10', 10". However, it will be appreciated that the fundamental optimization principles of the present invention are not limited to these collection procedures and/or apparatus.

[0287] As noted (FIGS. 1A-1D), the computer/database assembly 140 generally includes a central station 148, as well as a manipulation device 144 and a memory device 142 (not separately shown). Initially, it should be noted that the manipulation device 144 is preferably separate from the internal control of the blood component collection device 18. Device 18 also preferably remains accessible by the operator interface device 16 (which could include the touch screen introduced above). However, typically the manipulation device 144 will be integrated with (e.g., put in data communication relationship with) this internal control device 16. The central memory device may also be separate from the central manipulation device 144 (as well as from the individual blood processing machines 10 and/or their control elements 16). The memory device need only be put in data communication relationship with the data manipulation device 144 and/or one or more control elements of the central computational/database assembly 140 and/or one or more blood processing machines 10.

[0288] Referring now to FIG. 9A, the computational/database assembly 140 will be described with regard to a standard exemplary procedure. The central input station 148 will typically be used by blood banks/centers as the primary

means for donor data input and donor data management. As introduced above in the relation to FIGS. 2A-2E, information relating to a donor such as gender, height, weight, total blood volume, blood type, temperature, pressure and demographics will preferably be input at the central input station 148, or could be easily downloaded to the computer/database assembly 140 from a disparate system such as systems 3 and/or 4 as shown in FIG. 1B. Moreover, information relating to the donor's hematocrit and a blood component pre-count (such as platelet pre-count), both of which may be obtained from a donor blood sample and determined by known techniques such as cell counters, may also be entered at the central station 148. In addition to donor-related data, the particular type of collection procedure to be used for the donor (e.g. single needle or double needle) may be input/confirmed at the central input station 148. These also could be downloaded from a disparate system. Based upon this information and certain site-standardized conditions (e.g., total procedure time, collection efficiency, AC infusion rate), an initial procedure order is thereafter generated preferably by the manipulation device 140 which specifies the various process control parameters associated with the selected collection procedure.

[0289] The initial procedure order may be transferred/downloaded onto the internal control of a blood component collection device 18 by a computer network system (FIGS. 1A and 1B) or by other methods such as floppy disk transfer (not shown). The operator interface module 16 may be used to assist this process if required/desired. When this operator interface module 16 exists, it may of course still be used as an alternative for the initial donor data input and/or to generate the initial procedure order including optimization and thereby alleviate the need for a central input station 148. However, it is believed that it will be more efficient to use the central input station 148 and the associated central data manipulation device 140, preferably in conjunction with the central memory database. Although this initial procedure order may be used in the collection process, the initial procedure order may also be optimized in accordance with principles of the present invention to obtain one or more optimal values for the process control parameters. This optimization may also be performed on the individual blood processing machines 18, but is preferably conducted on/by the central data manipulation device 140. As noted, this optimization process may be utilized before the collection procedure is actually initiated, but may also be initiated during a given collection procedure and such is referred to as downstream optimization although if performed after initiation, and though possibly performed at the central computer/database 140 on by manipulation device 140, it is preferred that post-initiation changes be effected only at or by the individual machines 10.

[0290] With regard to the various optimization options, process control parameters may be derived for a product-based optimization. More particularly, the computer/database assembly 140 and specifically the manipulation device 144 derives process control parameters for achieving a predetermined yield of blood components through a maximization of at least one process parameter as will be discussed below in relation to the optimization models 152 (FIG. 9B), and 172 (FIG. 9C), for example, as noted above, in the United States a single platelet product (SPP) is 3×10^{11} platelets and a double platelet product (DPP) is 6×10^{11} platelets. Consequently, the manipulation device 144 may be

configured to provide a number of product-based optimizations such as SPP and DPP. Although the exact values for a current U.S. SPP and DPP could be configured into the manipulation device 144, in order to increase the probability that the actual yield will equal or exceed the yield requirements for a current U.S. SPP or a DPP, the site may configure a SPP to be 3.5×10^{11} platelets and a DPP to be 7.0×10^{11} platelets (e.g., to effectively provide a given confidence level over the minimum that the specified yield will actually be met).

[0291] The manipulation device 144 may also be configured to provide a time-based optimization. That is, for a given amount of time which a donor is available, the manipulation device 144 will derive those process parameters which allow for the collection of a "maximum" amount of platelets in this time period in relation to a maximization of at least one of the process control parameters.

[0292] Once the optimization is complete, the values for the various process control parameters generated thereby, as well as any ancillary/previously specified values, are downloaded to the internal control of the blood collection device 18 such that the collection procedure may be initiated or reinitiated (downstream optimization) as the case may be in accordance with these values. Once the procedure is completed, certain data is transferable (electronically through the communication subsystem 146 or otherwise as noted, e.g., floppy disk) back to the manipulation device 144 and/or the central memory/database and/or the central input station 148 for further use with regard to the particular donor. In addition, this information as well as the initial input may be used to generate various types of reports which may further assist in the management of the blood bank/center (e.g., individual run, donor/patient, summary reports, etc.). That is, this information may be used in the derivation of subsequent procedure orders for the particular donor or even for improved efficiency for entire pool of donors. For instance, in the event that a certain AC infusion rate was used in the collection procedure which had certain effects on this particular donor, this may be recorded in the central memory/database 142 such that a lower AC infusion rate would be suggested/required for subsequent donations by this donor and perhaps also for the entire pool.

[0293] One model which may be incorporated into the manipulation device 144 is illustrated in FIG. 9B and will be described with regard to platelet collections in accordance with the dual needle configuration of FIG. 7A, although the device 144 may be used with a variety of other collection procedures and including the single needle configuration of FIG. 7B, as well as with various other blood components. Initially, it should be noted that all references in FIG. 9B to "derivations" are actually provided by the prediction model discussed above such that there is either an appropriate communication interface between the prediction model and manipulation device 144 or the manipulation device 144 actually includes the prediction model disposed thereon or therein. Moreover, as noted the prediction model described here is specific to the blood component collection machine 18 and to platelet collections. Therefore, if other machines are used, the associated prediction model would also likely change as noted. Moreover, the associated prediction model may also vary in the case where different blood components such as red blood cells are to be collected.

[0294] The optimizer model 152 of FIG. 9B may be used for both product-based and time-based optimizations. Initially, the optimizer model 152 will be described with regard to a product-based optimization. That is, the fundamental premise of the optimization is to achieve a predetermined platelet (or other blood component type) yield (or within a yield range), preferably in the minimum amount of time.

[0295] The optimizer model 152 of FIG. 9B is comprised of four iterative loops. Generally, the first loop 156 is a derivation of an inlet flow (Q_{IN}) associated with a specified AC infusion rate (I_{SPEC}) which is typically set at a maximum value for purposes of the present invention and which is entered at the input station 154. This derivation is thereafter performed by the processing station 158 and includes the solution of Eqs. 4, 8, 14, and 16 and/or equations ancillary thereto by the prediction model as discussed above.

[0296] There are of course various convergence criterion/criteria which may be incorporated into the first loop 156. For instance, convergence may be based upon the current inlet flow (Q_{IN-C}) in the first loop 156 through use of a binary search technique. In this case, in solving the noted equations at the processing station 158 certain parameters remain fixed in the iterative derivation of the inlet flow (Q_{IN}) which achieves the specified AC infusion rate (I_{SPEC}) and these parameters are also specified at input station 154. These include the total blood volume (V_B) which can be calculated using Eq. 10 since the donor's height, weight, and gender are entered at the central input station 148, and the AC ratio (R), which can be calculated using Eq. 9 since the donor's hematocrit (H) has been determined, or may be specified at some value. Moreover, the total procedure time (t_P) remains fixed in each iterative derivation of the inlet flow (Q_{IN}) associated with the specified AC infusion rate (I_{SPEC}) in the first loop 156. However, since the total procedure time (t_P) is not known in the case of a product-based optimization and thus cannot be specified at the input station 154, a current total procedure time (t_{P-C}) initially will be assumed (e.g., this assumption is configured in the optimizer model 152 and since a range of total procedure times is provided in the prediction model 20 as noted above, the mean total procedure time (t_P) is typically configured into this portion of the optimizer model 152 as the initial current total procedure time (t_{P-C})). The "current" designation is used for the total procedure time in this case since the optimizer model 152 provides for an adjustment of the total procedure time after each iterative determination of the inlet flow (Q_{IN}) which provides the specified AC infusion rate (I_{SPEC}) in the second loop 160 in order to achieve the desired yield (Y) if required in the case of a product-based optimization as will be discussed in more detail below.

[0297] Generally, the inlet flow-based binary search technique convergence may be provided by assuming a current value for the inlet flow (Q_{IN-C}), calculating a current plasma collect factor (P_C) using the current total procedure time (t_{P-C}), calculating a current AC infusion rate (I_C) using the current inlet flow (Q_{IN-C}) and current plasma collect factor (P_C), and adjusting the current inlet flow (Q_{IN-C}) (at the parameter update in the first loop 156) in accordance with the selected binary search technique until there is a predetermined convergence between the two most recent values for the current inlet flow (Q_{IN-C}) (i.e., wherein the difference between the two most recent values of Q_{IN-C} is less than some predetermined amount which means that the conver-

gence criterion is met). In the case of a binary search technique, there will always be convergence (i.e., the convergence criterion will always be met) such that the optimizer model 152 will always exit the first loop 156 and enter the second loop 160.

[0298] As an alternative to the noted inlet flow-based convergence criterion/criteria and the noted binary search technique, another possibility is to base convergence on the specified AC infusion rate (I_{SPEC}) and use an iterative derivation to determine the desired inlet flow (Q_{IN}). In this case, the first loop 156 is used to once again iteratively derive the inlet flow (Q_{IN}) which provides the specified AC infusion rate (I_{SPEC}) at the processing station 158 from certain specified parameters. That is, the first loop 156 is still a maximization of the inlet flow (Q_{IN}) based upon the specified AC infusion rate (I_{SPEC}) which should be associated with the donor 14. This is again primarily through the solution of Eqs. 4, 8, 14, and 16 and/or equations ancillary thereto by the prediction model discussed above.

[0299] For purposes of solving the above-identified equations in relation to the infusion rate-based convergence criterion, certain parameters remain fixed in the iterative derivation of the inlet flow (Q_{IN}) which achieves the specified AC infusion rate (I_{SPEC}) in the first loop 156 and these parameters are also specified at the input station 154. These include the specified AC infusion rate (I_{SPEC}) which is known and which is typically a maximum value for the donor 14, the total blood volume (V_B) which can be calculated using Eq. 10 since the donor's 14 height, weight, and gender are entered in the central input station 148 or downloaded from a disparate information database, and the AC ratio (R) which can be calculated using Eq. 9 since the donor's 14 hematocrit (H) has been determined and input in the central input station 148 or otherwise downloaded, or may be entered as modified input data. Moreover, the total procedure time (t_P) remains fixed in each iterative derivation of the inlet flow (Q_{IN}) associated with the specified AC infusion rate (I_{SPEC}). However, once again the total procedure time (t_P) is not known in the case of a product-based optimization and thus cannot be specified at the input station 154. Therefore, a current total procedure time (t_{P-C}) initially will be assumed (e.g., this assumption is configured in the optimizer model 152, and since a range of total procedure times is provided in the prediction model as noted above, the mean total procedure time (t_P) is typically configured into the first loop 156 of the optimizer model 152). The "current" designation for the total procedure time is used for the above-identified reasons relating to the adjustment of the total procedure time in the second loop 160 if required to attain the desired yield (Y).

[0300] The solution of Eqs. 4, 8, 14, and 16 also requires that certain values be assumed for certain of the remaining parameters with still other parameters being derived from this assumption. In this case, an iterative procedure is used and updated/current values are used in the next iterative calculation(s). All parameters which change on each iteration of the first loop 156 are identified herein with a "c" subscript to designate that the most current value is to be used. Although the derivation of that inlet flow (Q_{IN}) which provides the specified AC infusion rate (I_{SPEC}) may be accomplished in a variety of manners via Eqs. 4, 8, 14, and 16, one way is to assume a current value for the plasma collect factor (P_C), then calculate the current inlet flow

($Q_{IN,C}$) using the specified AC infusion rate (I_{SPEC}), then calculate the current yield (Y_C), then calculate the current plasma collection factor (P_C) using the current yield (Y_C), and repeat this procedure with the current values until there has been acceptable convergence on the current inlet flow ($Q_{IN,C}$) in relation to the specified AC infusion rate (I_{SPEC}) (e.g., when the particular convergence criterion/criteria is met/established). When there is acceptable infusion rate-based convergence, the optimizer model 152 exits the first loop 156 and enters the second loop 160. In order to offer protection for cases when there is no such convergence, a maximum number of iterations for the first loop 156 may be specified (not shown).

[0301] The second loop 160 of the optimizer model 152 is a total procedure time (t_P) iteration. That is, the second loop 160 is an iterative adjustment of the current total procedure time ($t_{P,C}$). Initially, in the second loop 160 and in the case of a product-based optimization the model 152 will never exit at the first comparator 162 since a total procedure time (t_P) is not specified at the input station 154. Consequently, the optimizer model 152 proceeds to the second comparator 166 where convergence criteria (i.e., more than one check) is made. One convergence criterion which is checked at the second comparator 166 is whether the current yield (Y_C) is greater than or equal to the desired and specified yield (Y). In this case, the current yield (Y_C) may be calculated based upon the values specified at the input station 158, values derived at the processing station 158, and the current total procedure time ($t_{P,C}$) for comparison with the desired and specified yield (Y) (in some cases, this current yield calculation (Y_C) may have been performed in the first loop 156 and need not be repeated in the second loop 160). If the yield convergence criterion is met, the model 152 exits the second loop 160 and actually exits all the way through to the exit 151, as will be discussed below. In this case, the specified/derived values are "optimal" and the collection procedure could be performed on the device 18 using the noted values for the various control parameters.

[0302] In the event that the yield-based criterion is not met at second comparator 166, the second comparator 166 looks to a total procedure time-based convergence criterion which may be similar to that discussed above with regard to the inlet flow-based criterion (e.g., using a binary search technique with the convergence criterion then being a predetermined difference between the two most current values of the total procedure time ($t_{P,C}$)). On the first time through the second loop 160 after the noted yield-based convergence criterion has failed and the total procedure time convergence criterion has failed, the current total procedure time ($t_{P,C}$) is adjusted and the model 152 returns to the first loop 156. That is, each time that the current total procedure time ($t_{P,C}$) is adjusted in the second loop 160, the entirety of the first loop 152 is repeated (i.e., a new inlet flow (Q_{IN}) associated with the specified AC infusion rate (I_{SPEC}) is derived using the current total procedure time ($t_{P,C}$) provided by the adjustment in the second loop 160). Other convergence criterion/criteria could be used in the second loop 160, such as specifying a maximum number of iterations to be performed by the second loop 160.

[0303] In the event that the yield-based convergence criterion is not met on the second loop 160 and the total procedure time-based convergence criterion is met at the second comparator 166 in the second loop 160, the optimizer

model 152 exits the second loop 160 and enters the third loop 164. The third loop 164 is an iterative adjustment of the AC ratio (R). However, the model 152 initially enters the third comparator 169 where convergence criteria (i.e., more than one) are checked. One convergence criterion is again the above-noted yield-based convergence criterion. If this yield-based convergence criterion is again not met, an AC ratio-based convergence criterion is checked at the third comparator 169. This may be similar to the inlet flow-based criterion discussed above (e.g., using a binary search technique with the convergence criterion being the two most current values of the AC ratio). On the first time through the third loop 164 after the yield-based criterion has failed and the AC ratio-based convergence criterion has failed, the AC ratio is adjusted and the optimizer model 152 returns to the first loop 152. That is, each time that the AC ratio (R) is adjusted in the third loop 164, the entirety of the first and second loops 156, 160, respectively, is repeated. Other convergence criterion/criteria could be used in the third loop 164, such as specifying a maximum number of iterations of the third loop 164.

[0304] In the event that the yield-based convergence criterion is not met in the second or third loops 160, 164, respectively, and the second and third comparator 166, 169, respectively, and the AC ratio-based convergence criterion is met at the third comparator 169 in the third loop 164, the optimizer model 152 exits the third loop 164 and enters the fourth loop 168. The fourth loop 168 is an iterative adjustment of the specified AC infusion rate (I_{SPEC}). However, the optimizer model 152 initially enters the fourth comparator 170 where convergence criteria (i.e., more than one) are checked. One convergence criterion is the noted yield-based convergence criterion. If the noted yield-based convergence criterion is not met at the fourth comparator 170, an AC infusion rate-based criterion is checked at the fourth comparator 170. This may be similar to the inlet-flow based criterion discussed above (e.g., using a binary search technique with the convergence criterion being the two most current values of the AC infusion rate). On the first time through the fourth loop 168 after the yield-based criterion has failed and the AC infusion rate-based convergence criterion has failed, the AC infusion rate is adjusted and the model 152 returns to the first loop 152. That is, each time that the specified AC infusion rate (I_{SPEC}) is adjusted, the entirety of the first, second and third loops 156, 160, 164, respectively, is repeated (with the AC ratio set back to its initial value as entered at the input station 154 on each iteration of the fourth loop 168). Other convergence criterion/criteria could be used in the fourth loop 168, such as specifying a maximum number of iterations of the fourth loop 168. In cases where the specified AC infusion rate (I_{SPEC}) is actually the maximum AC infusion rate, typically the fourth loop 168 will execute only a single time with a one-time increase in the AC infusion rate of, for instance, 20% (e.g., may be site-configured).

[0305] In the foregoing loops where a yield-based convergence criteria are identified, when the criteria are met the optimizer model 152 exits to exit 151 and the specified/derived (i.e., current) values for the various process control parameters may be provided to the device 18 for performing the collection procedure. However, there may be cases where no optimization occurs, such as when the optimizer model 152 exits to the exit 151 based upon the AC infusion rate based convergence criterion being met.

[0306] The optimizer model 152 may also be used for a time optimization. That is, the optimizer model will derive optimal process parameters for a predetermined total procedure time (t_p) through maximization of at least one of the process parameters in order to maximize the platelet collection (or for other blood component types). In this case, the optimizer model 152 only executes the first loop 156 to derive the inlet flow (Q_{IN}) associated with a specified AC infusion rate (I_{SPEC}) (typically a maximum value) using the input total procedure time (t_p) in this iterative derivation instead of the assumed total procedure time (t_p) referenced above. Once there is acceptable convergence as defined above in the product-based optimization such that model 152 exits the first loop 156, the current yield (Y_C) may be calculated in the first loop 156 (but again may already have been calculated in the first loop 156 at the processing station 158 such that no further calculation is required) and the convergence criterion will be met at the first comparator 162 when entering the second loop 160 (i.e., in a time-based optimization when a total procedure time is specified at the input station 154, the model 152 will exit when entering the second loop 158). As a result, the inlet flow (Q_{IN}) and AC infusion rate (I) will be optimal and the collection procedure may be performed with such values.

[0307] Another optimization model is presented in FIG. 9C and may be used for both product-based and time-based optimizations. As in the case of the optimizer model 152, the optimizer model 172 may interface with the prediction model or actually integrally incorporate the prediction model, and thus reference to Eqs. 1-22 will be further made herein. Generally, the optimizer model 172 is based upon the principle that optimization occurs when an optimal inlet flow (Q_1) associated with an optimum system collection efficiency is used in the derivation of various process control parameters. Referring to FIG. 10, a representative inlet flow (Q_{IN})/yield (Y) curve is presented to show the optimal inlet flow (Q_1) associated with the maximum yield (Y_{MAX}). This optimal inlet flow (Q_1) is mathematically expressed by Eq. 23 presented below which results from differentiating Eq. 4 of the prediction model with regard to the inlet flow (Q_{IN}). As can be appreciated, where different algorithms are used in the associated prediction model (whether based upon collection of blood components other than platelets, different collection apparatus, or alternative derivations of the various parameters with the same collection procedure and apparatus), the optimal inlet flow may be mathematically expressed in a different manner.

$$Q_L = \left(\frac{C_1}{2C_2} \right) e^{-0.99(1-1/R)H} - C_3 \quad (\text{Eq. 23})$$

$$C_3 = \frac{1}{2(t_p/K_7 - 1/K_9)}, \quad \begin{matrix} Q_0 \geq 45 \text{ for Dual Needle ("DN")} \\ \geq 20 \text{ for Single Needle ("SN")} \end{matrix} \quad (\text{Eq. 24})$$

$$Q_0 < 45 \text{ for DN} < 20 \text{ for SN} \quad (\text{Eq. 25})$$

$$K_7 = 500(DN) \quad K_9 = 45(DN) = 215(SN) \quad 20(SN) \quad (\text{Eq. 26})$$

$$C_1 = 0.803(SN, DN \text{ without stepdown}) = 0.840(DN \text{ with stepdown}) \quad (\text{Eq. 27})$$

$$C_2 = 4.08 \times 10^{-5}(DN) = 854 \times 10^{-5}(SN) \quad (\text{Eq. 28})$$

[0308] Based upon the foregoing, the optimal inlet flow (Q_1) is really "optimal" in terms of the collection apparatus.

[0309] Referring again to FIG. 9C, the optimizer model 172 will initially be described with regard to a product-based optimization wherein the desired yield (Y) is specified at input station 184. Generally, the inlet flow (Q_{IN}) associated with a specified AC infusion rate (I_{SPEC}) (typically the maximum AC infusion rate and also specified at input station 184) is iteratively derived from certain other specified parameters. This inlet flow calculation, particularly when the maximum AC infusion rate (I_{MAX}) and maximum AC ratio (R_{MAX}) are specified, the inlet flow (Q_{IN}) is optimal based on the physiological considerations of the donor 14. This is primarily through the solution of Eqs. 4, 8, 14, and 16 and/or equations ancillary thereto by the prediction model discussed above. For purposes of solving these equations certain parameters remain fixed in the iterative derivation of the inlet flow (Q_{IN}) which achieves the specified AC infusion rate (I_{SPEC}) and these parameters are also specified at input station 184. These include the total blood volume (V_B) which can be calculated using Eq. 10 since the donor's height, weight, and gender are entered in the central input station 148, and the AC ratio (R), which can be calculated using Eq. 9 since the donor's hematocrit (H) has been determined, or may be specified at some maximum value. Moreover, the total procedure time (t_p) remains fixed in each iterative derivation of the inlet flow (Q_{IN}) associated with the specified AC infusion rate (I_{SPEC}). However, since the total procedure time (t_p) is not known in the case of a product-based optimization and thus cannot be specified at the input station 184, a current total procedure time (t_{p-C}) initially will be assumed (e.g., this assumption is configured in the optimizer model 172 and since a range of total procedure times is provided in the prediction model as noted above, the mean total procedure time (t_p) is typically configured into this portion of the optimizer model 172 as the initial current total procedure time (t_{p-C})). The "current" designation is used for the total procedure time in this case since the optimizer model 172 provides for an adjustment of the total procedure time after each iterative determination of the inlet flow (Q_{IN}) which provides the specified AC infusion rate (I_{SPEC}) in order to achieve the desired yield (Y) if required in the case of a product-based optimization as will be discussed in more detail below.

[0310] The solution of Eqs. 4, 8, 14, and 16 also requires that certain values initially be assumed for certain of the remaining parameters. In this case, an iterative procedure is used in the solution of the yield equation (Eq. 4) (and including equations ancillary thereto as noted above) and updated values are used in the next iterative calculation(s) at the processing station 188. Although the derivation of that inlet flow (Q_{IN}) which provides the specified (typically maximum) AC infusion rate (I_{SPEC}) may be accomplished in a variety of manners via Eqs. 4, 8, 14, and 16, one way is to assume a current value for the plasma collect factor (P), then calculate the current inlet flow (Q_{IN-C}) using the specified AC infusion rate (I_{SPEC}), then calculate the current yield (Y_C), then calculate the current plasma collection factor (P_C) using the current yield (Y_C), and repeat the foregoing with the updated parameters, all within the processing station 188, until there has been acceptable convergence on the current inlet flow (Q_{IN-C}) in relation to the specified AC infusion rate (I_{SPEC}).

[0311] In addition to the calculation of the current inlet flow (Q_{IN-C}) associated with the specified AC infusion rate (I_{SPEC}), the above-discussed optimal inlet flow (Q_1) is

calculated at processing station 192. Consequently, a comparison can be made between the current inlet flow (Q_{IN-C}) which was derived in the above-described manner and the optimal inlet flow (Q_I) at the first comparator 176. If the current inlet flow (Q_{IN-C}) is less than the optimal inlet flow (Q_I) at the first comparator 176, the specified values for the various parameters associated with the inlet flow Q_{IN} are "optimum", namely the AC ratio (R) and the AC infusion rate (I) specified at the input station 184. Thereafter, the current yield (Y_C) (which was calculated in the derivation of the current inlet flow (Q_{IN-C}) associated with the specified AC infusion rate (I_{SPEC}) at the processing station 188) is compared with the input yield (Y) at second comparator 180. In the event that there has been acceptable convergence between these yield values, the current total procedure time (t_{P-C}) is also "optimal". However, in the event that there has not been acceptable convergence between these yield values, the current total procedure time (t_{P-C}) is adjusted at adjusting station 196 and the foregoing iterative derivation of the current inlet flow (Q_{IN-C}) associated with the specified AC infusion rate (I_{SPEC}) is repeated until such convergence is achieved (i.e., using the initially specified AC infusion rate (I_{SPEC}) and the now adjusted current total procedure time (t_{P-C}), a new current inlet flow (Q_{IN-C}) is iteratively derived in the above-described manner).

[0312] Referring back to the first comparator 176, if the current inlet flow (Q_{IN-C}) associated with the specified AC infusion rate (I_{SPEC}) derived at processing station 188 is greater than the optimal inlet flow (Q_I), a current AC infusion rate (I_C) associated with this particular inlet flow (Q_I) is iteratively derived at the processing station 188 generally in the above-described manner (i.e., the initially specified AC infusion rate (I_{SPEC}) is disregarded in this derivation and a current AC infusion rate (I_C) is iteratively derived to coincide with the inlet flow (Q_I)). In this case, the current inlet flow (Q_{IN-C}) will always be equal to the optimal inlet flow (Q_I) at the first comparator 176 and the optimizer model 172 thereafter proceeds to the second comparator 180 for the yield comparison in accordance with the above-described procedure.

[0313] The optimizer model 176 may also be used for a time-based optimization. In this case, the total procedure time (t_P) is specified at the input station 184 as a specified total procedure time (t_{P-SPEC}) and thus is not assumed as in the product-based optimization. The optimizer model 172 thereafter proceeds in the same manner discussed above with regard to the product-based optimization except at the second comparator 180. Since no yield was input there is no yield comparison made at the second comparator 180. Instead a total procedure time comparison is made at the second comparator 180. Since the current total procedure time (t_{P-C}) was set equal to the specified total procedure time (t_{P-SPEC}) prior to the model 172 proceeding to the processing station 188 in this time-based optimization, the model 172 will exit each time at the second comparator for a time-based optimization.

[0314] In addition to the above-described product-based and time-based optimizations, the principles of the present invention may be extended to other applications relating to enhancing blood component system management. For instance, an optimization in accordance with principles of the present invention may be extended to encompass donor management issues. In one such case, another "optimiza-

tion" associated with the blood component collection process would be to collect blood components as dictated by existing inventory (i.e., use optimization as an inventory control). That is, information relating to the inventory of the various types of blood components in the blood bank/center and/or the demand for one or more blood component types could be maintained such that specific collection procedures could be selected to accommodate for a low supply of a given blood component type and/or a high demand for such blood component type. More specifically, in the event that the supply of red blood cells was low and/or the demand for red blood cells was high, or anticipated to be so in the near future, prompts could be provided to operators that red blood cells should be selected for collection if possible from donors during a given time period. Relatedly, the optimization principles of the present invention would be applicable to maintaining data on blood component collections from a given donor such that a determination could be made as to what type or types of blood components from the particular donor provided the maximum yield in the collection procedure. That is, information could be collected and maintained from prior blood component donations such that a determination could be made for a specific donor as to which type or types of blood components the donor has had a propensity to produce maximum yields therefor.

[0315] Notwithstanding the foregoing description of the present invention in relation to an on-line blood component collection process, those skilled in the art will appreciate that the source of blood may be provided to the blood component collection device from an appropriate blood container (not shown) interconnected with the blood component collection device 18 versus receiving such directly from a human donor. Moreover, the blood of course may be provided from alternative sources such as animals. Furthermore, as illustrated in FIG. 7B the described component (platelet, RBC, plasma, inter alia) harvesting procedure may be performed utilizing a single needle configuration. In addition, the present invention is applicable to the collection of other types of blood components such as red blood cells, stem cells, white blood cells, and/or plasma, and is further applicable to the simultaneous collection of more than one blood component type. In the case of red blood cell collection and optimization in accordance with principles of the present invention, the donor's blood type should be known and used in various algorithms. Moreover, the present invention is not limited to the source being whole blood. That is, the principles of the present invention may be applicable to removal of a component from any composite liquid, i.e. any liquid containing separable components (preferably separable using mechanical procedures).

[0316] The foregoing description of the present invention has been presented for purposes of illustration and description. Although the preferred embodiment of the invention has been described in language which may be thought specific to structural features, methodological acts, and computer readable media containing such acts, it is rather intended to be understood that the invention defined in the appended claims is not necessarily limited to the specific structure, acts or media so described. The specific structure, acts or media are disclosed as preferred forms of implementing the claimed invention. Consequently, variations and modifications commensurate with the above teachings, and skill and knowledge of the relevant art, are within the scope of the present invention. The embodiments described here-

inabove are further intended to explain best modes known of practicing the invention and to enable others skilled in the art to utilize the invention, and such other embodiments, and with various modifications required by the particular applications or uses of the present invention. It is intended that the appended claims be construed to include alternative embodiments to the extent permitted by the prior art.

What is claimed is:

1. An extracorporeal blood processing information management system comprising:

- a central database;
- a data input device connected in data communication relationship with said central database;
- a data manipulation device connected in data communication relationship with at least one of said central database and said data input device; and
- a communication subsystem connected in data communication relationship with at least one of said central database, said data input device and said data manipulation device; and

at least one extracorporeal blood processing machine;

whereby said communication subsystem is connected in data communication relationship with said at least one extracorporeal blood processing machine to provide for data communication to and from said at least one extracorporeal blood processing machine;

whereby said communication subsystem communicates data to said at least one extracorporeal blood processing machine, said data being preparation data which is generated by said data manipulation device and is used by said at least one extracorporeal blood processing machine in preparation of said at least one machine for an extracorporeal blood processing procedure; and

whereby said communication subsystem communicates data from said at least one extracorporeal blood processing machine, whereby said data is run data which represents information about an extracorporeal blood processing procedure run on said at least one blood processing machine.

2. An extracorporeal blood processing information management system adapted to be used with at least one extracorporeal blood processing machine, said system comprising:

- a central database;
- a data input device connected in data communication relationship with said central database;
- a data manipulation device connected in data communication relationship with at least one of said central database and said data input device; and
- a communication subsystem connected in data communication relationship with at least one of said central database, said data input device and said data manipulation device;

whereby said communication subsystem is also adapted to be connected in data communication relationship with at least one extracorporeal blood processing machine to

provide for data communication to and from said at least one extracorporeal blood processing machine;

whereby said communication subsystem is adapted to communicate data to said at least one extracorporeal blood processing machine, said data being preparation data which is generated by said data manipulation device and is used by said at least one extracorporeal blood processing machine in preparation of said at least one machine for an extracorporeal blood processing procedure; and

whereby said communication subsystem is adapted to communicate data from said at least one extracorporeal blood processing machine, whereby said data is run data which represents information about an extracorporeal blood processing procedure run on said at least one blood processing machine.

3. An extracorporeal blood processing information management system according to claim 2 whereby said preparation data is derived from data communicated from said central database to said data manipulation device.

4. An extracorporeal blood processing information management system according to claim 2 whereby said preparation data is derived from data communicated from said data input device to said data manipulation device.

5. An extracorporeal blood processing information management system according to claim 2 in which said preparation data is communicated from at least one of said central database and said data input device to said data manipulation device.

6. An extracorporeal blood processing information management system according to claim 2 in which said run data is communicated by said communication subsystem from said at least one extracorporeal blood processing machine during said procedure.

7. An extracorporeal blood processing information management system according to claim 2 in which said run data represents information about an extracorporeal blood processing procedure collected after completion of said procedure.

8. An extracorporeal blood processing information management system according to claim 2 in which said run data is communicated to said at least one extracorporeal blood processing machine and used by said at least one extracorporeal blood processing machine in preparation of said at least one machine for a discrete, subsequent extracorporeal blood processing procedure.

9. An extracorporeal blood processing information management system according to claim 2 in which said run data is communicated by said communication subsystem to said central database to create stored run data,

10. An extracorporeal blood processing information management system according to claim 9 in which said stored data is communicated by said communication subsystem to said data manipulation device which manipulates said stored data to create preparation data which is communicated to one of said at least one extracorporeal blood processing machine which uses said preparation data in preparation of said one of said at least one machine for a discrete, subsequent extracorporeal blood processing procedure.

11. An extracorporeal blood processing information management system according to claim 2 in which a report may be generated using said run data.

12. An extracorporeal blood processing information management system according to claim 2 in which said preparation data is manipulated by said manipulation device to create manipulated preparation data.

13. An extracorporeal blood processing information management system according to claim 12 in which said manipulated preparation data is optimized preparation data as a result of an optimization manipulation performed by said manipulation device.

14. An extracorporeal blood processing information management system according to claim 2 in which said central database receives previously stored data from a discrete information management system, and wherein said previously stored data is communicated by said communication subsystem to said data manipulation device which manipulates said previously stored data to create said preparation data.

15. An extracorporeal blood processing information management system according to claim 14 in which said preparation data is optimized preparation data as a result of an optimization manipulation performed by said manipulation device.

16. An extracorporeal blood processing information management system according to claim 2 which further comprises computer program product including:

- a module for collecting donor data;
- a module for manipulating said donor data;
- a module for assigning a donor to an extracorporeal blood processing system; and
- a module for finalizing an extracorporeal blood procedure.

17. An extracorporeal blood processing information management system according to claim 16 in which said module for collecting donor data includes one or more sub-procedures which prompt a user to enter data.

18. An extracorporeal blood processing information management system according to claim 16 in which said module for collecting donor data includes one or more sub-procedures which provide for receiving donor data stored in a discrete storage medium.

19. A system according to claim 16 wherein said module for manipulating donor data includes one or more facilities which provide for optimizing donor data to create optimized donor data.

20. A system according to claim 16 wherein said module for manipulating donor data includes one or more facilities which provide for manipulating said optimized donor data to create manipulated donor data.

21. A system according to claim 16 whereby said module for collecting data and said module for manipulating data are used to obtain a prediction of a procedure for which a donor is qualified to undergo recruiting a donor to undergo the procedure.

22. A system according to claim 16 wherein said module for assigning a donor to an extracorporeal blood processing system includes one or more facilities which provide for determining the availability of a donor to be assigned to an extracorporeal blood processing system.

23. A system according to claim 16 wherein said module for assigning a donor to an extracorporeal blood processing system includes one or more facilities which provide for

determining the availability of an extracorporeal blood processing system to which a donor may be assigned.

24. A system according to claim 16 wherein said module for finalizing an extracorporeal blood procedure includes one or more facilities which provide for monitoring a procedure.

25. A system according to claim 16 wherein said module for finalizing an extracorporeal blood procedure includes one or more facilities which provide for finalizing a procedure.

26. A system according to claim 16 wherein said module for finalizing an extracorporeal blood procedure includes one or more facilities which provide for generating a report on a procedure.

27. A system according to claim 16 which further comprises a module for monitoring a procedure.

28. A system for performing an extracorporeal blood collection procedure according to claim 16 which further comprises a reporting module for generating reports.

29. A system for performing an extracorporeal blood collection procedure according to claim 16 which further comprises a reporting module for administrating parameters to be used in at least one of said module for collecting donor data; said module for manipulating said donor data; said module for assigning a donor to an extracorporeal blood processing system; and said module for finalizing an extracorporeal blood procedure.

30. An extracorporeal blood processing information management system for use with one or more extracorporeal blood processing machines, said system comprising:

- a central database;
- a data input device connected in data communication relationship with said central database;
- a data manipulation device connected in data communication relationship with at least one of said central database and said data input device; and
- a communication subsystem connected in data communication relationship with at least one of said central database, said data input device and said data manipulation device;

whereby said communication subsystem is also connected in data communication relationship with one or more extracorporeal blood processing machines to provide for data communication in at least one direction to or from said one or more extracorporeal blood processing machines; and

whereby said communication subsystem is also connected in data communication relationship with a discrete information management system to provide for data communication in at least one direction to or from said discrete information management system.

31. An extracorporeal blood processing information management system according to claim 30 in which said communication subsystem communicates data from said discrete information management system to said extracorporeal blood processing information management system.

32. An extracorporeal blood processing information management system according to claim 31 whereby said communication subsystem further communicates the data from said discrete information management system to said one or more extracorporeal blood processing machines, said data

being used by said one or more extracorporeal blood processing machines in preparation of said one or more machines for an extracorporeal blood processing procedure.

33. An extracorporeal blood processing information management system according to claim 31, in which said data from said discrete information management system is manipulated by said data manipulation device to create manipulated preparation data which is communicate to said one or more extracorporeal blood processing machines, said manipulated preparation data being used by said one or more extracorporeal blood processing machines in preparation of said one or more machines for an extracorporeal blood processing procedure.

34. An extracorporeal blood processing information management system according to claim 33 in which said manipulated preparation data is optimized preparation data as a result of an optimization manipulation performed by said data manipulation device.

35. An extracorporeal blood processing information management system according to claim 30 whereby said communication subsystem communicates data from said one or more extracorporeal blood processing machines to said extracorporeal blood processing information management system, whereby this data is run data which represents information about an extracorporeal blood processing procedure run on said one or more blood processing machines.

36. An extracorporeal blood processing information management system according to claim 35 whereby said communication subsystem communicates said run data from said extracorporeal blood processing information management system to said discrete information management system, whereby this run data represents information about an extracorporeal blood processing procedure run on said one or more blood processing machines.

37. An extracorporeal blood processing information management system according to claim 30 whereby said discrete information management system is a discrete extracorporeal blood processing information management system.

38. An extracorporeal blood processing information management system according to claim 37 whereby said discrete extracorporeal blood processing information management system is also connected in data communication relationship with a discrete set of one or more extracorporeal blood processing machines in data communication in at least one direction to or from said discrete set of said one or more extracorporeal blood processing machines.

39. An extracorporeal blood processing information management system according to claim 38 whereby said discrete extracorporeal blood processing information management system further includes:

- a discrete central database;
- a discrete data input device connected in data communication relationship with said discrete central database;
- a discrete data manipulation device connected in data communication relationship with at least one of said discrete central database and said discrete data input device; and
- a discrete communication subsystem connected in data communication relationship with at least one of said discrete central database, said discrete data input device and said discrete data manipulation device;

whereby said discrete communication subsystem is also connected in data communication relationship with said discrete set of one or more extracorporeal blood processing machines to provide for data communication in at least one direction to or from said discrete set of one or more extracorporeal blood processing machines.

40. An extracorporeal blood processing information management system according to claim 39 whereby said discrete communication subsystem of said discrete extracorporeal blood processing information management system communicates data to said discrete set of one or more extracorporeal blood processing machines, said data being communicated from said extracorporeal blood processing information management system and said data being preparation data which is generated by said data manipulation device and used by discrete set of said one or more extracorporeal blood processing machines in preparation of said discrete set of one or more extracorporeal blood processing machines for an extracorporeal blood processing procedure.

41. An extracorporeal blood processing information management system according to claim 39 whereby said discrete communication subsystem communicates data from said discrete set of one or more extracorporeal blood processing machines, whereby this data is run data which represents information about an extracorporeal blood processing procedure run on said discrete set of one or more extracorporeal blood processing machines.

42. An extracorporeal blood processing information management system according to claim 30 whereby said discrete information management system is a discrete blood center information management system.

43. An extracorporeal blood processing information management system according to claim 30 whereby said discrete information management system is a discrete hospital information management system.

44. An extracorporeal blood processing information management system according to claim 30 whereby said discrete information management system is a discrete help center information management system.

45. An extracorporeal blood processing information management system according to claim 30 whereby said discrete information management system is a discrete internet information management system.

46. An extracorporeal blood processing information management system according to claim 30 whereby said discrete information management system is a discrete manufacturers' information management system.

47. A method for managing extracorporeal blood processing comprising the steps of:

receiving stored donor data from a storage medium; manipulating said stored donor data using a data manipulation device to obtain manipulated data, said data manipulation device being disposed in data communication relationship with said storage medium and an extracorporeal blood processing machine; communicating said manipulated data from said data manipulation device to said extracorporeal blood processing machine; and performing an extracorporeal blood processing procedure using said manipulated data.

48. A method for performing an extracorporeal blood collection procedure including the steps of:

collecting donor data;

manipulating said donor data to create manipulated donor data;

assigning a donor to an extracorporeal blood processing system including sending said manipulated donor data to the extracorporeal blood processing system;

running an extracorporeal blood collection procedure using said manipulated donor data and creating run data; and

finalizing an extracorporeal blood collection procedure.

49. A method according to claim 48 wherein said step of collecting donor data includes receiving donor data from a storage medium, and wherein said step of manipulating said donor data includes manipulating the donor data received from said storage medium.

50. A method according to claim 48 wherein said step for collecting donor data includes one or more facilities for prompting a user to enter data.

51. A method according to claim 48 wherein said step for collecting donor data includes one or more facilities which provide for receiving donor data stored in a discrete storage medium.

52. A method according to claim 48 wherein said step for manipulating donor data includes one or more facilities which provide for optimizing donor data to create optimized donor data.

53. A method according to claim 48 wherein said step for manipulating donor data includes one or more facilities which provide for manipulating said optimized donor data to create manipulated donor data.

54. A method according to claim 48 whereby said step for collecting data and said step for manipulating data are used to obtain a prediction of a procedure for which a donor is qualified to undergo recruiting a donor to undergo the procedure.

55. A method according to claim 48 wherein said step for assigning a donor to an extracorporeal blood processing system includes one or more facilities which provide for determining the availability of a donor to be assigned to an extracorporeal blood processing system.

56. A method according to claim 48 wherein said step for assigning a donor to an extracorporeal blood processing system includes one or more facilities which provide for determining the availability of an extracorporeal blood processing system to which a donor may be assigned.

57. A method according to claim 48 wherein said step for finalizing an extracorporeal blood procedure includes one or more facilities which provide for monitoring a procedure.

58. A method according to claim 48 wherein said step for finalizing an extracorporeal blood procedure includes one or more facilities which provide for finalizing a procedure.

59. A method according to claim 48 wherein said step for finalizing an extracorporeal blood procedure includes one or more facilities which provide for generating a report on a procedure.

60. A method according to claim 48 which further comprises a step for monitoring a procedure.

61. A method according to claim 48 which further comprises a step for generating reports.

62. A method according to claim 48 which further comprises a step for administrating parameters to be used in at least one of said steps for collecting donor data; for manipu-

lating said donor data; for assigning a donor to an extracorporeal blood processing system; and for finalizing an extracorporeal blood procedure.

63. A method according to claim 48 in which each of said steps may be performed at any time during an extracorporeal blood processing procedure.

64. A method according to claim 48 in which said step for collecting donor data produces a checked-in donor record which contains said donor data; said checked-in donor record being used by said step for manipulating donor data to create manipulated donor data.

65. A method according to claim 48 in which said step for manipulating produces a manipulated donor data record which contains said manipulated donor data; said manipulated donor data record being used by said step for assigning a donor to an extracorporeal blood processing machine to assign a donor to a machine.

66. A system for performing an extracorporeal blood collection procedure including a computer program product comprising:

a module for collecting donor data;

a module for manipulating said donor data; and

a module for assigning a donor to one of one or more extracorporeal blood processing systems; and

a module for finalizing an extracorporeal blood procedure.

67. A method for managing extracorporeal blood processing activities comprising the steps of:

using a centralized system to run a prediction using donor data;

obtaining a prediction of a yield for a extracorporeal blood procedure for which a donor is qualified to undergo;

contacting the donor to recruit the donor to undergo the procedure.

68. A method according to claim 67 in which the centralized system comprises a database, and a data manipulation device.

69. A method according to claim 67 in which step of using a centralized system comprises collecting donor data, and manipulating said donor data.

70. A method according to claim 69 in which step of collecting donor data comprises receiving data from a discrete storage medium.

71. A method according to claim 69 in which step of collecting donor data comprises receiving data from a data input device.

72. A method according to claim 69 in which step of manipulating donor data comprises running an optimization on said donor data to obtain optimized donor data.

73. A method according to claim 72 in which step of manipulating donor data comprises running an optimization on said donor data to obtain optimized donor data.

74. A method according to claim 73 in which step of running an optimization on said donor data to obtain optimized donor data further comprises obtaining a prioritization of potential procedures.

75. A method according to claim 67 which is used to control inventory.

76. A method according to claim 67 which is performed without the specific potential donor present.

77. A method according to claim 67 which is performed tailor its blood and blood component supply to better match demand.

78. A method for prioritizing extracorporeal blood component collection procedures comprising the steps of:

manipulating donor data on a data manipulation device to obtain manipulated data;

communicating said manipulated data to an extracorporeal blood processing machine; and

performing an extracorporeal blood collection procedure using said manipulated data.

79. A method for managing extracorporeal blood component collection according to claim 78 wherein said manipulated data is process control data.

80. A method for managing extracorporeal blood component collection according to claim 78 wherein said manipulated data is optimized process control data.

81. A method for managing extracorporeal blood component collection according to claim 78 further comprising the step of communicating run data from said extracorporeal blood processing machine to said data manipulation device.

82. A method for managing extracorporeal blood component collection according to claim 81 further comprising the step of generating a report using said run data.

83. A method for collecting at least one predetermined type of blood component from a source of whole blood using a blood component collection system comprising a blood component collection device and a collection procedure,

said collection procedure having a plurality of control parameters associated therewith, said method comprising the steps of:

providing biological data relating to said source of whole blood;

obtaining historical data from a centralized database; identifying at least one of a desired yield of said at least one predetermined blood component or a time period for duration of the collection procedure;

performing a first deriving step comprising deriving a magnitude for at least one of said control parameters from at least two of said providing, obtaining and identifying steps;

using said magnitude of said at least one of said control parameters obtained during said first deriving step to control the operation of said blood component collection system; and

performing said collection procedure on said blood component collection device using said at least one of said control parameters obtained during said first deriving step to control at least one of the collection of said desired yield of said at least one predetermined blood component from said source of whole blood or the time period of duration of said collection procedure.

* * * * *

UNOS **VITALINK**

Business System Concept

November 30, 1993

UNOS United Network
for Organ Sharing

AMS

American Management Systems, Inc.

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1. EXECUTIVE SUMMARY

American Management Systems, Inc. (AMS) is pleased to present the United Network for Organ Sharing (UNOS) with the first deliverable of the Vitalink prototype, the Business System Concept Document. AMS combines extensive mobile computing technology expertise with the wireless communication experience necessary to develop the Vitalink system. AMS is looking forward to developing a partnership with UNOS in the development and implementation of a full-scale Vitalink system. AMS, headquartered in Fairfax, Virginia, is one of the nation's largest consulting and development firms with over 30 offices worldwide.

Vitalink is a data collection tool designed for the unique requirements of the organ sharing community. It is application software combined with pen-based, hand-held computers and wireless data communications. Vitalink will not dramatically *change or re-engineer* the current donor data collection process, rather it will compress the existing process so that a recipient can be found for an organ in the least amount of time. UNOS's number one objective for Vitalink is to save lives by reducing the amount of time it takes to find a suitable recipient.

Vitalink will be used by the Organ Procurement Coordinators in the field to collect and transmit the essential donor information to the UNOS Organ Center so that a match run can be executed on the existing system at UNOS. Vitalink provides a mechanism to standardize the data that is collected on donors to increase the chance of organ placement. Vitalink allows the coordinators to collect and transmit the donor data wherever and whenever the information becomes available.

The Vitalink prototype automates the data on the Association of Organ Procurement Organizations' (AOPO) form. The plan is to deliver the front-end user interface in early January, 1994. The back-end wireless communications will be incorporated by the end of January, 1994 for prototype delivery in February. Full-scale implementation is planned for late summer of 1994 after a thorough review of the prototype feedback.

2. INTRODUCTION

This document is the blueprint for development and implementation of the Vitalink prototype system. Like a blueprint for a building, it addresses the purpose of Vitalink, what Vitalink will include and how Vitalink will be built. This document also addresses the development of a partnership between AMS and UNOS to develop a complete production system of Vitalink by the summer of 1994.

The key to the design of Vitalink is a comprehensive, but user friendly interface combined with seamless communications. The organ sharing environment is in a constant fight against time. The Vitalink system will promote the use of accurate, quality data that can be used to find a recipient for an organ in the least amount of time possible.

The initial plan to release a prototype of the Vitalink system by January, 1994 was developed as a cost-effective way to perform a proof-of-concept study and begin the relationship between AMS and UNOS in the development of a production version of Vitalink.

This document is created to be a living guide to the overall design and construction of Vitalink. Changes to Vitalink's purpose and design are certain to occur over time. These changes should be incorporated in this document since it is the cornerstone of the Vitalink system.

The Business System Concept begins with an overview of Vitalink. An approach section follows and includes a detailed description of the communication tools that will be applied in the Vitalink application. A projected cost and development schedule are also included in this document.

3. BACKGROUND

3.1 United Network for Organ Sharing (UNOS)

Originally established in 1977 by members of the South-Eastern Organ Procurement Foundation (SEOPF), the United Network for Organ Sharing (UNOS) operates the national Organ Procurement and Transplantation Network (OPTN) and the national Scientific Registry for Organ Transplantation. In this role, UNOS functions as both a contractor for the federal government and as a private, non-profit corporation. Under contract with Health Resources and Services Administration (HRSA), UNOS has operated the OPTN since September 30, 1986, and the Scientific Registry since September 30, 1987.

In October of 1984, Congress passed The National Organ Transplant Act (NOTA), which provided for the establishment of a Task Force on Organ Procurement and Transplantation, an Organ Procurement and Transplantation Network, and a Scientific Registry for Organ Transplantation. In 1986, upon completion of the work of the Task Force, HRSA called for proposals to establish the OPTN. In September 1986, a contract was awarded to UNOS to operate the OPTN. In September 1987, UNOS was awarded a separate contract to establish and operate the Scientific Registry for Organ Transplantation. Both contracts were renewed in 1990 and 1993 for three years.

The OPTN and Scientific Registry contracts are administered by the Division of Organ Transplantation, a division of HRSA, within the Department of Health and Human Services (DHHS). Under the terms of these contracts, UNOS conducts numerous projects to meet federally-established goals of the OPTN and the Scientific Registry. As required by the Scientific Registry contract, all data collected and generated under the contract are the exclusive property of the United States Government.

The purpose of the Scientific Registry, as stipulated in the NOTA of 1984, is the collection of data for continuous evaluation of the clinical and scientific status of transplantation in the United States. The specific goals of the Registry are the following: 1) to collect, in a computer system, data on all transplant recipients and all transplant programs in the US, 2) to provide a database enabling periodic analysis and reporting of transplantation effectiveness, nationwide, and 3) to provide a national database for basic and clinical research on organ transplantation. The Scientific Registry collects data about recipient status at the time of transplant and at time of post-transplant hospital discharge. The Registry also collects follow-up data on transplant recipients until two years following graft failure or until the patient dies, regardless of the cause of death.

Since its inception, the purpose of the OPTN has been "...to improve the effectiveness of the nation's organ donation, procurement, and transplantation system by increasing the availability of and access to donor organs for patients with end-stage organ failure."¹ In an effort to achieve these goals, the OPTN

¹ From HRSA Request for Proposals for OPTN contract

operates and maintains a national computer list of patients waiting for kidney, heart, heart/lung, lung, liver, and pancreas transplants. It also maintains a computer-assisted system for allocating organs to individuals on the waiting list, as well as an Organ Center allowing 24-hour access by all transplant programs in the US to the donor/recipient matching system. Data collected by the OPTN pertains to patients waiting for transplants, donors and recipients of donated organs, donor/recipient matching and organ allocation, and donor/recipient histocompatibility. In order to operate the OPTN, UNOS has adopted corporate by-laws and policies governing membership standards, organ allocation, and data management.

UNOS members fall into one of two categories: 1) institutional members and 2) public members. Institutional members include transplant centers, independent organ procurement organizations, and independent tissue typing laboratories. Among public members are 1) private, non-profit voluntary health organizations which promote organ donation or which serve interests of transplant patients and their families, 2) private, non-profit medical/scientific organizations involved in transplantation, or 3) representatives of fields such as theology, ethics, health care financing, and other areas.

For administrative purposes, UNOS has divided the country into eleven geographic regions. Each region is assigned a UNOS staff administrator to assist in coordinating regional activities. Additionally, each region is represented on the Board of Directors and on each of UNOS's permanent standing committees.

3.2 American Management Systems, Inc.

American Management Systems, Inc. is based in Fairfax, Virginia. Founded in 1970, AMS specializes in the helping clients improve their performance through the intelligent use of information technology. AMS combines specific industry experience, business function expertise, proven systems development practices, and an extraordinary depth of technological competence to help our clients meet their business goals.

AMS is a trusted business partner for many of the largest and most respected organizations in the markets in which we specialize. We derive approximately 85% of our business each year from clients with whom we worked in the previous year.

AMS mobilizes specific industry experience, functional expertise, and technical resources to serve clients worldwide. AMS's 3,700 employees serve clients from our headquarters in Fairfax, Virginia and from offices in over 30 cities throughout North America and Europe. AMS has sustained an annual growth rate of approximately 20% for the past decade. Our revenues for 1992 were \$333 million.

AMS's technology leadership in mobile computing is well known by government and industry. We have invested significantly in research and development to improve our knowledge of portable computers and wireless communications so that we can better assist our customers. The AMS Mobile Computing Center

has developed over twenty production and prototype systems in the last two years for some of the largest government and Fortune 500 organizations. The total potential user audience for AMS mobile systems will eclipse 2500 users by the end of 1994.

3.3 Vitalink Partnership

UNOS and AMS were introduced in 1992 by GRiD Systems, Inc., the industry leader in mobile computers. Greg Pellegrino, AMS's Director for Mobile Computing, met with Dave Klein, UNOS Director of Computer Services, to discuss the application of hand-held computers and wireless communications to the organ placement process. AMS combined proven methods and previous mobile computing experience to design a prototype development approach for UNOS.

Vitalink is the name given by UNOS to the future system developed through this collaborative effort to apply state of the art technology for gathering and disseminating electronic data directly from the donor site. Vitalink's benefits will yield improvements throughout the organ data management process.

AMS is contracted to develop the initial Vitalink prototype. AMS's initial approach is based on a quick schedule and practical cost in the spirit of establishing a long-term partnership with UNOS. This document is the first deliverable produced by this relationship, and will lay the cornerstone for defining a plan for the full implementation of Vitalink.

3.4 Technology Trends

There are three absolute trends in the evolution of computer technology:

1. They are getting more powerful.
2. They are getting smaller.
3. They are getting cheaper.

While some experts argue the merits of one computer or another, one operating system versus another, or one Graphical User Interface (GUI) versus another, these three trends will forever affect the successful application of computers to improve business performance.

It is interesting to note that since the day Charles Babbage completed his programmable machine in 1870, computers served much the same purpose as his original device for over 100 years. Crunching numbers was and still continues to be the most common use of the world's most powerful computing devices. After all, the word computer originally referred to a person who performed mechanical calculations.

It is not so significant that the *personal* computer invented in the 1970's was smaller than its predecessors. The significance was the *potential* the *smaller* computing device would have for the productivity of individuals. The computer is still immature in its application to improve the productivity of individuals and

entire organizations. The problem is not the device, it is our ability to apply it correctly.

All significant technological innovations have had a similarly long gestation period. That is, the technology user took a long time to figure out how to put it to use without creating new problems. The types of problems that are most common are cultural acceptance, fragility or added work. Yes, additional work has often been required during the long periods of technology adoption.

An example of this was provided by Michael Rothschild in his article "The Coming Productivity Surge," Forbes ASAP Magazine, March 29, 1993. Rothschild uses this example of the electric motor and its impact on manufacturing:

"As the 20th century began, business investment in electrical equipment skyrocketed. Between, 1900 and 1920 the percentage of US factories equipped with electric motors jumped from five percent to fifty-five percent. Yet, despite the obvious advantages of electric motors over steam engines, worker productivity showed almost no measurable increase.

Solving the riddle of today's computer productivity is simple, once its century-old predecessor is understood. Back then, a state-of-the-art facility was a three- or four-story brick building. A coal-fired steam engine sat in the factory's basement. Its power was transmitted to the equipment on the floors above through an elaborate system of vertical and horizontal shafts and drive belts.

Factory owners began replacing steam engines with large electric motors because the new technology slashed coal bills by 20 to 60 percent. But the power generated by these first electric motors was still conveyed to lathes, drills, grinders and punch presses by the conventional system of shafts and belts. As time passed and somewhat smaller electric motors became affordable, separate motors were installed on each floor. This eliminated the need for the vertical shaft. However, because the motors were still relatively expensive, each one powered a group of machines via horizontal shafts and belts.

Electric motor technology was indeed revolutionary, but to pay for itself it had to be grafted onto the existing industrial infrastructure. Multistory factories made sense in the steam age because they reduced the costly friction losses incurred as horizontal shafts carried power to the equipment. Single-floor factories would have eliminated all the labor wasted moving unfinished goods from floor to floor, but overall it was cheaper to staff the elevators than to pay for the coal turned to waste heat by long horizontal shafts.

For similar reasons, machines requiring the most horsepower were placed near the base of each floor's horizontal shaft. Smaller, low-power-consuming equipment sat at the far end of the work floor. Again, though this arrangement made economic sense from a power-conservation standpoint, it made the flow of materials ridiculously inefficient. In short, since the entire industrial infrastructure had evolved around the assumption of expensive steam power, factories were designed to be grossly inefficient in other dimensions. Once made, these fundamental economic trade-offs endured for decades.

It wasn't until cheap, small electric motors became available in the 1920s that factories began to abandon "group drive" power for the "unit drive" approach, the familiar present day system in which each machine is powered by its own internal motor. As this technology was installed, companies ripped out their drive shafts and belts, rearranged their machines and smoothed their flow of materials. The most innovative high-tech firms - companies in fast-growing, new industries such as cigarettes, organic chemicals and electrical equipment - were the first to go all the way and take the radical step of building single-story factories. They were literally the first flattened corporations.

Finally, forty years after Edison's breakthroughs, productivity growth took off. Where the annual labor productivity growth had hovered around one percent for the first two decades of the century, it jumped to more than five percent a year during the Roaring Twenties".

Michael Rothschild, "The Coming Productivity Surge", Forbes ASAP Magazine, March 29, 1993

Rothschild's analogy is included here to better understand the natural pace with which we figure out the right ways to apply technology. Motors were initially used to provide a continuous source of lower cost power. Likewise, computers initially provide a consistent, quick way of performing large calculations. Our understanding of these complex tools evolves once we address short term objectives (speed and reduced cost) while improving the form-factor (smaller and smaller), and solving new social impact issues as well.

This brings us to the question of the value of computer technology for productivity. What is productivity? Simply, productivity is a measure of useful outputs. Even though reduced energy costs were a primary motivator in adapting the electric motor, it is the re-engineered manufacturing processes that improved individual productivity.

Today's technology trends address form-factor and flexibility for information management. Smaller computers give us more capacity and capability wherever we need to manage information, just as miniature motors provide rotating machinery for the smallest process in a factory. New databases, wireless communications and application software tools provide the flexibility necessary to avoid new burdens for information workers, just like small motors that can be placed anywhere.

Vitalink is important because it capitalizes on the evolution of both information technology and the way we make use of it. There are still "shafts and pulleys" in

the organ transplantation process today. Vitalink enables coordinators to quickly disseminate vital organ information at the donor site and get quick feedback. Like the motor in Rothschild's example, Vitalink does not change processes itself. Rather, Vitalink will support a compressed workflow that will yield benefits to decision makers and stakeholders, including the donor families and recipients.

3.5 System Concept Study

AMS firmly believes in performing an initial requirements study with the developers and users of an information system. This process establishes a solid foundation for software development and a strong sense of ownership for the future users of the Vitalink system.

Representatives from AMS and UNOS met on Tuesday November 9, 1993 at UNOS headquarters in Richmond, Virginia. This initial meeting outlined the goals, objectives and schedule of the Vitalink prototype system. By early January, 1994 UNOS and AMS will produce an operational prototype for the donor data collection process. The back-end communications will be ready for prototype delivery in February, 1994. The location and number of test sites will be determined by UNOS before prototype delivery in February. The specific hardware to be used for the prototype will be determined after AMS presents UNOS a review of the pen-based products of several hardware vendors. The plan for full implementation of Vitalink will be developed as part of the partnership established between AMS and UNOS.

November 9, 1993 Vitalink Kick-Off Meeting

David Klein	UNOS, Director of Computer Services
Scott Hall	UNOS, Vitalink Project Manager
Dan Stockdreher	UNOS, Manager of Organ Center
Greg Pellegrino	AMS, Director of Mobile Computing
Lisa Wolsh	AMS, Vitalink Project Manager

AMS and UNOS representatives met again on Monday November 15, 1993 in Richmond to analyze the Organ Procurement process at UNOS. This meeting outlined the current process that is in operation to gather and transmit donor information from the donor site to UNOS. The current method used by the Organ Procurement Coordinators (OPC) in the field is time consuming and cumbersome. The 12 page Association of Organ Procurement Organizations (AOPO) form, or something like it, is either faxed to the UNOS Organ Center or verbally repeated to the Organ Procurement Specialist at the Organ Center. This process is naturally prone to data entry errors or misinterpretations at the coordinator's and the specialist's end. The Vitalink system will promote consistent, accurate, quality data, without the problems inherent in a hand-written, form-driven process.

November 15, 1993 Preliminary Analysis Meeting

David Klein	UNOS, Director of Computer Services
Scott Hall	UNOS, Vitalink Project Manager

Greg Pellegrino AMS, Director of Mobile Computing

Lisa Wolsh AMS, Vitalink Project Manager

The following day, Lisa Wolsh and Scott Hall spent the morning at the Organ Center at UNOS. Each step of the donor process was reviewed with the Organ Procurement Specialist on duty. The entire 12 page AOPO form was discussed to review the attributes of the form and determine how Vitalink could improve the process for the Organ Procurement Specialist at the Organ Center.

The afternoon was spent with Dan Stockdreher reviewing the AOPO form to place an order of precedence on the essential data which Vitalink will send to UNOS initially to get the donor process moving at a rapid pace. Each section of the form was carefully evaluated and analyzed to determine how the current paper form would most effectively be presented in an electronic format.

November 16, 1993 Tour of Organ Center and Review of AOPO Form

Scott Hall UNOS, Vitalink Project Manager

Dan Stockdreher UNOS, Manager of Organ Center

Gray Granger UNOS, Organ Procurement Specialist

Lisa Wolsh AMS, Vitalink Project Manager

A meeting was arranged with Virginias' Organ Procurement Agency (VOPA) to review the donor data collection process from the OPO's and the individual coordinator's level. AMS learned that about one-half of the existing OPOs use the AOPO standard donor data collection form. The OPOs take the hand-written donor data form and re-enter the information into a database system for future reporting and reimbursement. Much of the data that is on the AOPO form is used again on subsequent forms required by UNOS and other involved parties. The idea of a mobile, pen-based, wireless communication software package to automate the donor data collection process was very well received by the VOPA Organ Procurement Coordinators.

November 19, 1993 Meeting with VOPA in Richmond and Charlottesville

Scott Hall UNOS, Vitalink Project Manager

Lisa Wolsh AMS, Vitalink Project Manager

Janice Watson VOPA, Executive Director

Gloria Taylor VOPA, Director of Education

Kevin Myer VOPA, BS, CPTC Organ Procurement Coordinator

Tim Johnson VOPA, BSN, RN, PTC Organ Procurement Coordinator

Lorelle Myer VOPA, Data Coordinator

Another meeting with the Indiana OPO is scheduled for December 10, 1993 in Indianapolis, Indiana.

4. APPROACH

Users of mobile computing technologies like pen-based computers and wireless communications often improve organizational effectiveness through re-engineered business processes. The role of these technologies is to *enable* the new processes. The justification to invest in these technologies comes from the financial benefits derived from the new processes. New processes achieved through the application of mobile computing can provide cost savings, added-cost avoidance or competitive advantage.

Vitalink is different because it initially does not change the business processes related to organ procurement and transplantation. The UNOS Vitalink system uses these new information technology tools to carry out their critical mission. This initial justification model is called Strategic Match. Strategic match is the alignment of information technology investments with the organization mission and goals. A strategic match approach often yields cost savings, cost-avoidance and competitive advantage, however those benefits are secondary to the global benefits of alignment.

The following statements illustrate this by describing the Health Resources and Services Administration (HRSA) goals for the National Organ Procurement and Transplantation Network (OPTN):

- Improve the effectiveness of cadaver organ procurement and distribution.
- Increase patient access to state-of-the-art transplantation technology.
- Improve the system for sharing renal and extra-renal organs so as to
 - facilitate matching of donors and recipients, based on specific criteria established for each organ,
 - improve transplantation outcomes,
 - provide a system by which immunologically sensitized patients are afforded the best possible opportunity to be matched with a compatible donor, and
 - decrease the wastage of organs.
- Assure quality control by collection, analysis, and publication of data on organ donation, procurement and transplantation.
- Maintain and improve professional skills of those involved in organ procurement and transplantation.

Vitalink supports improvements in each of these areas.

4.1 What Is Vitalink?

Vitalink is the combination of a pen-based computer, wireless communications and specialized software to automate the organ donor data collection process. Vitalink is not a new process, but rather a modified, compressed version of the current donor data collection process. Vitalink will impact three levels of

organizations and individuals; UNOS, Organ Procurement Organizations, and Organ Procurement Coordinators. Vitalink's role in each level is discussed in the following sections.

4.2 What Does Vitalink Do for UNOS?

UNOS's vision for Vitalink is to help save lives. Plain and simple, Vitalink is the automated version of a paper-driven, time-consuming donor data collection process. The amount of data needed for a potential donor will not be reduced, but Vitalink will help in the collection and transmission of that data to UNOS so that a recipient can be found as quickly as possible. Vitalink will be the vehicle used to collect standard donor data and send this data to UNOS. The Organ Center will initially receive this data in a paper report format, but will eventually receive this data into its computer system for on-line review to execute a match run.

Vitalink will ultimately be able to transmit the donor data to the Organ Center which will receive the data on-line. The Organ Center will then run the match and forward the donor data to the top thirty or forty transplant centers where the potential recipients are registered. Currently, the essential donor data is reaching at most five transplant centers per hour after a match run has been made. Vitalink will allow the Organ Procurement Specialist (OPS) at the Organ Center to spend more time finding a suitable recipient and less time tracking down donor data that is illegible or data that has been omitted or misinterpreted. The OPS will now receive standard data through Vitalink.

Vitalink will establish a close link between UNOS and the Organ Procurement Organizations working together for the common goal of saving lives. Vitalink will provide UNOS with leading edge technology to improve the performance of a paper driven data collection and dissemination process. UNOS will maintain and extend its leadership in the organ sharing community. UNOS will demonstrate to the Department of Organ Transplantation its ability to use advanced technology through Vitalink in the continuing effort to improve the OPTN and the accuracy of data collected for the Scientific Registry.

4.3 What Does Vitalink Do for an OPO?

Vitalink will improve the donor data collection process at the OPO level in several areas. Vitalink will be able to export donor data into a common relational database format that can be easily pulled into existing databases at individual OPOs. Vitalink will serve as a valuable addition to the existing information system products that an OPO may already have. This export feature of Vitalink will eliminate the need for dual data entry and the errors that normally accompany it.

Vitalink will improve the accuracy of the data that is collected on the donor. For example, each check on the donor's vital signs will be date and time stamped. The point when donor management begins will be accurately recorded. Accurate data is needed for proper reimbursement from HCFA. Vitalink will provide a more complete, easy to use data collection process that will record the actual expenses incurred by the OPO in the donor management process.

Vitalink could reduce the time between data capture and reimbursement since it eliminates a time consuming data entry step.

The number one goal of Vitalink is to get the essential donor information to UNOS as quickly as possible so that the donor's organs can be matched to a recipient on the waiting list. Approximately sixty people die a day waiting for an organ transplant. In addition to the lifesaving aspects of Vitalink, there are business risks at stake for the OPO when trying to recover organs from a donor. The OPO can incur costs between \$6,000 to \$20,000 to remove an organ from a donor whether or not it is placed. Vitalink will play an important role in transmitting the donor data to UNOS so that a recipient can be found as quickly as possible. The more organs that can be placed for a donor increases the revenue that the OPO can generate to cover the costs of organ procurement and placement.

4.4 What Does Vitalink Do for an OPC?

Vitalink will not change the process that a coordinator must go through when a donor becomes available. However Vitalink will change the mechanism used to collect and send the essential donor information to UNOS. A coordinator typically spends 18 to 72 hours at a donor site collecting and evaluating donor data in an extremely time-sensitive process. The fight against the clock is inherent in the donor management process. Vitalink will assist the coordinator in the collection and transmission of the donor data required to place the organ with an appropriate recipient.

The Organ Procurement Coordinator will use Vitalink to ease the paperwork burden of their job. Multiple forms with much of the same data needs to be hand-written several times during the collection process. Initially Vitalink will automate the 12 page AOPO form, but ideally it will be able to produce all of the standard UNOS forms needed for the donor management process.

The Vitalink system will allow the coordinator to record the donor data electronically on a tablet about the size of a clipboard. They will not be required to set up desk and chair for a portable PC, or be tied to a wall socket or fax machine. Instead the coordinator will be able to record the required information anytime, anywhere - in the hospital waiting room, at the OPO office site, or in the operating room. Vitalink will allow the coordinator to record donor data on the spot when and where it occurs. Vitalink will be the coordinators' mobile data collector and wireless communicator.

Vitalink will assist the coordinator in recording more accurate data. An automated version of the AOPO form will provide the coordinator with valid options for certain data fields reducing the possibility of human error or misinterpretation. The coordinators will be able to customize certain parts of Vitalink like displaying only a list of local area hospitals and transplant centers instead of all the possibilities in the entire state. Vitalink will provide a standard mechanism to record and send donor data to UNOS. The intuitive user interface will be efficient and easy to use. The results sent to UNOS will be in text format, therefore eliminating the time consuming need for call-backs because of illegible handwriting.

4.5 Data Systems at UNOS

Several database systems and accompanying processes support the organ procurement and transplantation process today.

The **OPTN Database** contains pre-transplant information pertaining to transplant candidates on the OPTN Waiting List, donor/recipient matching, cadaveric and living donors, histocompatibility and potential recipients. Much of the data are collected through a series of forms, Feedback Records, and Match Runs.

The Match Run is a computer program that compares transplant candidate characteristics stored on the OPTN Waiting List with donor information entered each time a cadaveric organ becomes available. For each donor organ, computerized matching algorithms are used to produce rank ordered lists of potential recipients. The matching algorithms used are based on UNOS/OPTN organ allocation policies, transplant center acceptance criteria and local variances. Each donor organ generates a separate and distinct computer list.

The **Scientific Registry** database stores post-transplant information pertaining to organ recipients. Data are collected on organ-specific registration and follow-up forms.

Because of a broad-based need, the UNOS Scientific Advisory Committee (SAC) has developed mechanisms through which the government, the scientific community, and the public can obtain access to OPTN and Scientific Registry Transplant data. UNOS makes data available for the study of scientific and policy-related issues:

Government Access. Federal, state and local governments all utilize OPTN/Scientific Registry data for the development of reimbursement policy, performance standards, legislative and regulatory policy.

Public and Scientific Community Access. Access to certain OPTN and Scientific Registry data must be made available to the public and the scientific community. The data are used for scientific research, policy analysis, and assessment of the efficacy of the organ allocation process. Current studies include the impact of matching on outcome, factors affecting patient waiting time, disease progression during the waiting period, and risk factors for graft failure.

UNOS-Funded Research Projects. To the extent that contract funds remain after operational expenses have been met, UNOS has used funds to support research projects approved by the HRSA Project Officer.

UNOS Data Requests. The UNOS Research Department receives requests for OPTN/Scientific Registry data from many different sources including the federal government, UNOS committees, UNOS members, UNOS staff, the media, private industry and other sources.

UNOS normally provides data to any individual or organization that requests it. If the information or data are readily available, the information is often provided immediately.

4.6 How Does Vitalink Work?

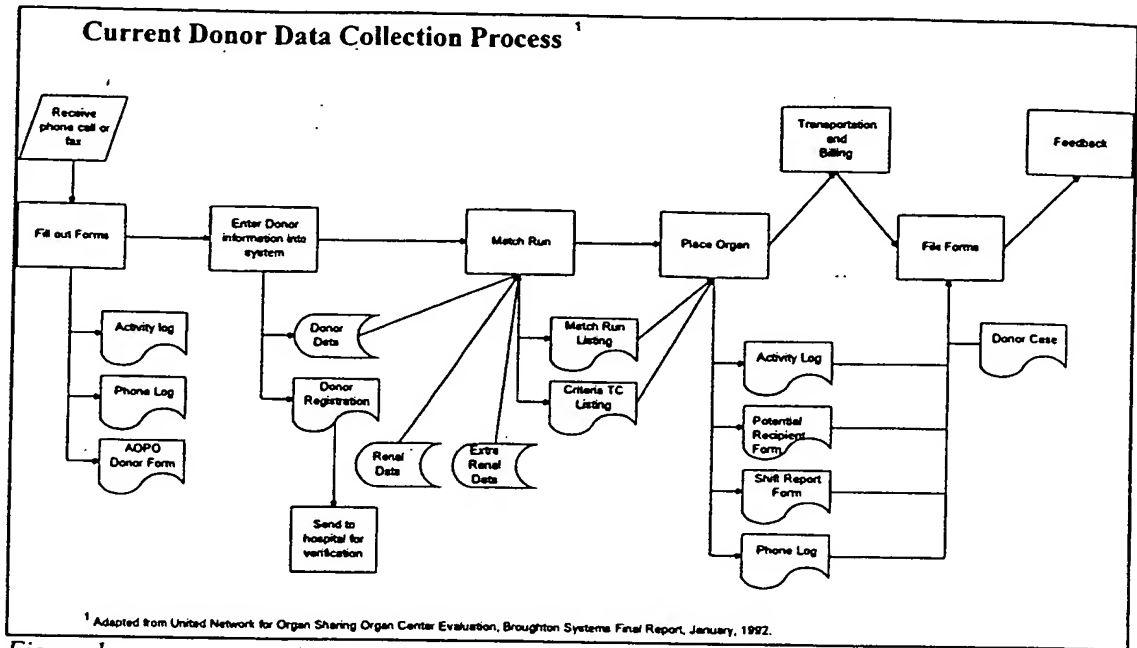


Figure 1

Figure 1 above illustrates the current work flow for the donor data collection process. Vitalink compresses the current processes by automating the AOPO donor data form and sending and receiving that data via wireless communications.

Figure 2 below is displayed with shaded areas which represent the areas and forms which Vitalink will affect. Vitalink creates a ripple affect which starts by transmitting the data directly from the coordinator to the UNOS Organ Center and trickles all the way through the process increasing efficiency and data accuracy.

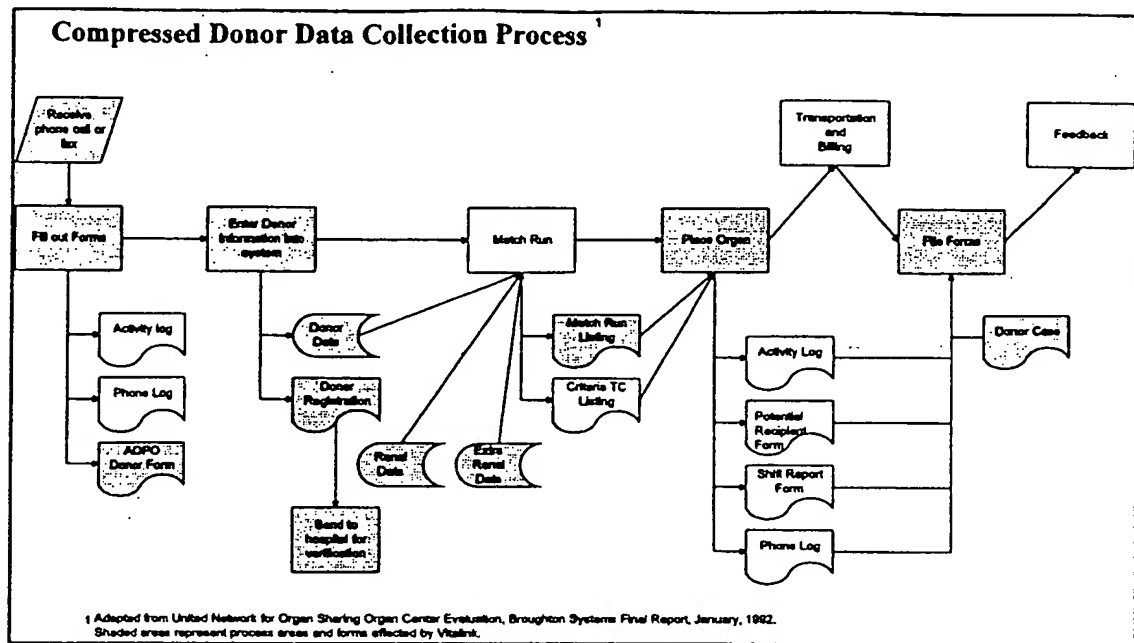
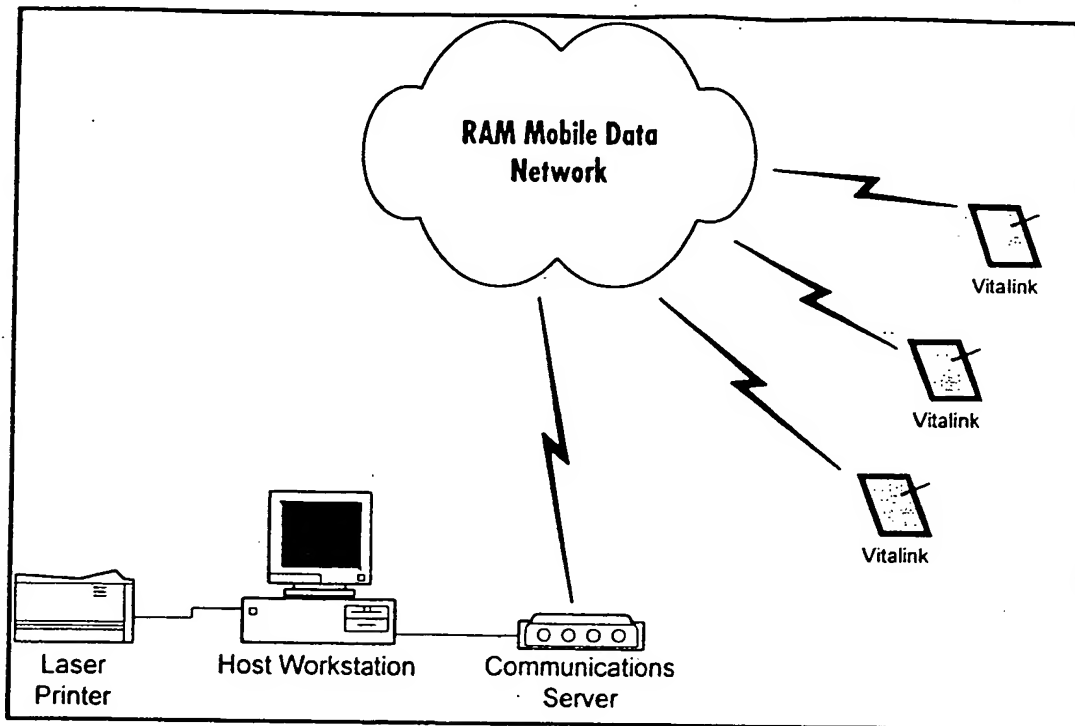


Figure 2

Vitalink will send donor data directly from the coordinator to the UNOS Organ Center. The donor data received will be modeled after the AOPO standard data collection form. Initially, this information will be transmitted from the coordinator and printed at the Organ Center for review by the Organ Procurement Specialist on duty. The donor data is also stored in an ASCII file format so that the data can be imported into the current UNOS system by a custom batch file routine developed by the UNOS Computer Services staff. Once the data is entered into the UNOS system, a match run can be executed. Ideally the match run listing will be sent to the transplant centers, hospitals, OPOs and coordinators wirelessly. All of the preceding steps will assist in the placement of the organs. Eventually UNOS will be able to send out a broadcast message to the top potential recipients on the waiting list either by fax or on-line.

4.7 Technical Architecture

The system architecture for Vitalink can be divided into three primary components: hardware, software, and the communication link between the field and the UNOS office. This section provides a summary of the relationship between the components at each system level.



4.7.1 Hardware

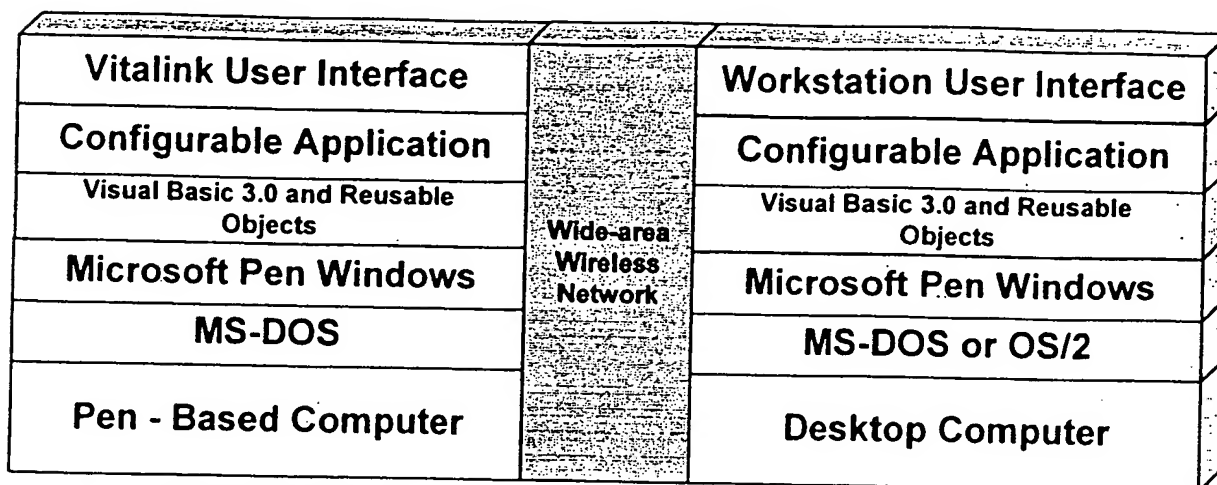
Field Units

Vitalink will first be developed to run on various types of pen-based computers. The minimum requirements for each unit is a 40 MB hard drive, 4MB RAM, and the capability to use the Microsoft Windows for Pen user interface. Peripherals and additional equipment vary by manufacturer.

Host Workstation

UNOS will be equipped with a host workstation to provide the means of accepting the wireless communications from the individual pen-based units in the field. The hardware components will include a communications server, hard drive, monitor, keyboard, and laser printer.

4.7.2 Software



Vitalink Platform Communications Desktop Workstation

The above figure illustrates the multiple software layers of the Vitalink application. The user interface allows the users to interact with the application, but transparent to the user is the underlying code and the operating system.

This system uses the Windows for Pen Computing interface and will be developed using Microsoft Visual Basic 3.0. AMS and other third party objects will be used for the graphical controls and system features. Functions not available in Visual Basic's native mode will be developed using Microsoft C/C++. During the prototype, each pen-based computer will be a dedicated system and only Vitalink will be accessible in the field. All other native Windows options will not be accessible by the user. This simplifies the system and controls the prototype test environment by preventing the user from having to navigate through layers of windows and icons to execute the application.

4.7.3 Communications

Data communications and transfer from remote sites will be performed using a wireless data network. This network will use the latest in wireless data transmission: cellular and packet-switched protocols. Both technologies are discussed in detail in section 5.3.

4.8 User Interface

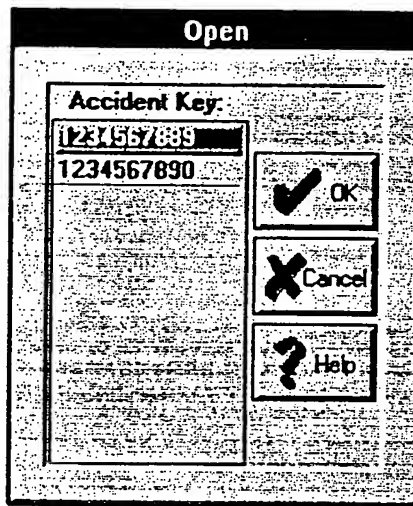
The Vitalink application uses Multiple Document Interface (MDI) for efficient interaction between the user and the information on the screen. MDI is a design concept used by software packages like Microsoft Word and Excel. It is characterized by a Parent control window with smaller Child windows within the workspace. MDI allows users to interact among multiple forms while using standard menu controls and buttons.

4.10 Creating A New Donor File

When a new donor is entered into the system, all current forms are saved, and the user is provided with a fresh report to begin the donor management process. Thus, a new report can be initiated at any time without losing any of the previously entered information.

4.10.1 Selecting a Previous Donor File

The coordinator will also be able to select a previously entered donor file, to review or edit some specific information, or to complete a partially entered report which was left unfinished at the donor site. An old record can be retrieved and edited by all system functions at any time.



Sample from the AMS Mobile Accident Reporting System

4.10.2 The Toolbar



Sample from the AMS Mobile Accident Reporting System

The toolbar is a row of functional buttons that appear at the top of the display screen, representing all major functions of the system. Each of the APO sections can be called from the toolbar, as well as a pop-up standard keyboard, communication links and the Windows help system. All of the activities on the toolbar can also be activated from the smaller, text menu bar, located just above the toolbar. This arrangement follows an established Microsoft Windows standard and provides an easy interface to all system capabilities as well as a quick access to all of the most-used functions.

4.10.3 The Data Bar and System Interface

The Data Bar, located just below the toolbar, and the report form workspace, are the system's main interface. When the coordinator selects a AOPO area from the toolbar, that section is shown in the workspace below. The Data Bar then serves as the main editing tool for the coordinator, collecting all of the data field information in various editor types. The Data Bar changes to react with the user and the form to edit each field in the report sections. Specific fields can also be selected non-sequentially by the user by tapping on the desired area of the report form. Command buttons on the Data Bar assist the user in navigating through the report section, clearing specified report fields, and providing context sensitive help based on the current field and established procedures on collecting the specific information.

The image shows a sample of the AMS Mobile Accident Reporting System interface. It features a title bar that reads "Enter Witness's Phone Number". Below the title bar, there are three input fields for the phone number: a three-digit area code field (labeled with a parenthesis and a dot), a three-digit exchange field (labeled with a hyphen), and a seven-digit number field (labeled with a hyphen). Below these fields is an "ext." label followed by a five-digit extension field. At the bottom of the interface is a numeric keypad with buttons for digits 1 through 0, a backspace key (labeled with a left arrow), and a help key (labeled with a question mark). To the right of the input fields are four command buttons: "Next" (with a right arrow), "Prev" (with a left arrow), "Reset" (with a circular arrow), and "Help" (with a question mark).

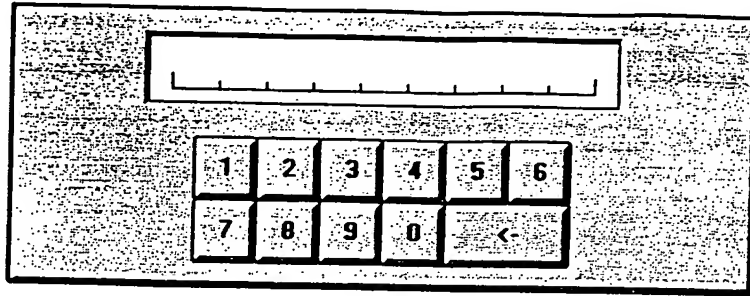
Sample from the AMS Mobile Accident Reporting System

4.10.4 Data Field Editors

There are two categories of data field editors that can appear on the Data Bar, data entry editors and data selection editors. The data entry editors provide the user with the capability of entering field information from pen/handwriting recognition or from keyboard input. These editors are used mainly with unstructured data collection, such as names and addresses. The data selection editors collect information that is more standardized through the use of button groups or code listings that apply to each field. Each editor type is described in detail in the following paragraphs.

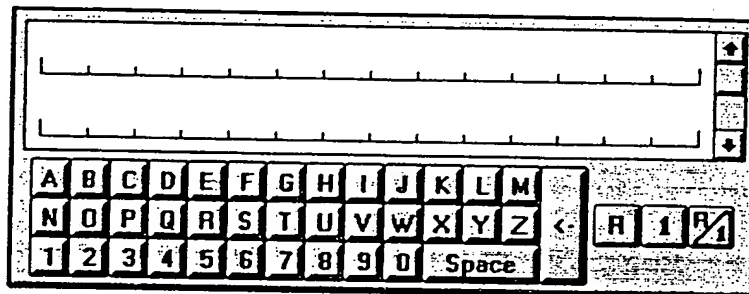
4.10.5 Numeric Entry

The numerical editor contains a pen-aware field which recognizes the users handwriting and translates the electronic ink written on the screen into a database record. To improve the recognition rate for this editor, the pen-aware field has been tailored to detect only numerical information. In addition, a numeric keypad is included on the editor as an alternative input device.



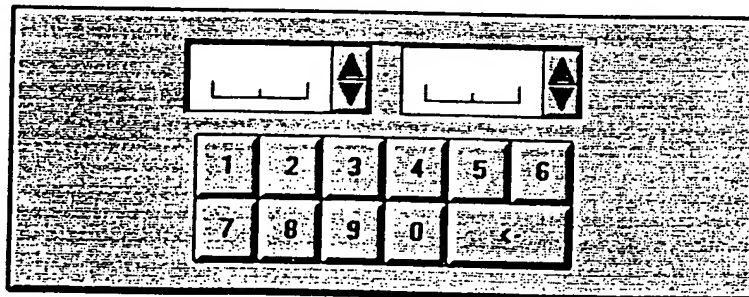
4.10.6 Text Entry

The text editor is similar to the numerical editor, however three controls are included to adjust the recognition of the pen-aware field to detect alphabetic characters only, numeric characters only, or full alpha-numeric recognition. A complete alpha-numeric keypad is also included to bypass the pen-aware field and to insure flexibility for the user.



4.10.7 Time Entry

The time entry editor is a customized version of the numeric editor which does not rely on handwriting recognition, and follows the basic standards of time entry in a 24 hour format. Time fields automatically pre-fill with the current system time provided by the computer's internal clock, and can be easily incremented or decremented by the user.



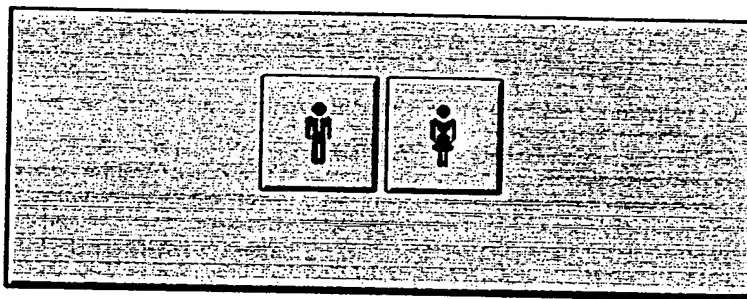
4.10.8 Date Selection

The date selection editor is composed of a calendar interface, in which the user can select the calendar day and increment or decrement the month or year. Like the time editor, the date editor also pre-fills with the current system date which will rarely need to be changed by the user.

September				1993		
Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

4.10.9 Gender Selection

A simple male/female selection editor will be provided for all gender related fields. This editor associates the appropriate code to gender information.



4.10.10 Listing Selection

For all fields containing non-specialized or non-graphical selection options, a text listing will be provided for the user to select the appropriate code number based on standard codes and text descriptions. These lists eliminate the need for the user to memorize the codes for each field.

01 - Adair
02 - Adams
03 - Allamakee
04 - Appanoose
05 - Audubon
06 - Benton
07 - Black Hawk
08 - Boone

4.10.11 Donor Information

The data entry form is displayed on the screen much like the paper version.

Iowa DOT - Mobile Accident Reporting System Form#: 12345678

File Edit Options Tools Window Help

Icons: Car, Accident, Fire, Medical, Police, etc.

MARS
Mobile Accident Reporting System
Copyright 1998
American Management Systems, Inc.

Next
Prev
Clear
Help

Unit Form - Unit #1

Driver's Full Name - Last, First, Middle
Address, City, State, Zip

Date of Birth, Gender, Driver License Number, State, License Restriction, Restriction Completed With
Citation Number, Citation Charge, Phone, Chemical Test Given?, Test Results

Owner's Full Name - Last, First, Middle
Address, City, State, Zip

Year, Make, Model, Style, License Plate No, state, Year, Vin No.

Vehicle Type Code, Special Use Code, Total Occupants
Attachment, Fire Explosion, Hit and Run, Removal Authority

Vehicle Removed by, Point of Initial Impact, Damaged Area of Vehicle
Vehicle Removed to, Damage Severity Code, Vehicle Defect
Approximate Cost to Repair or Replace, Initial Direction Travel, Speed Limit

CIRCUMSTANCES
Roadway/Environment Related
Contributing Circumstances
Driver Condition
Driver/Vehicle Related Contributing Circumstances (up to two)

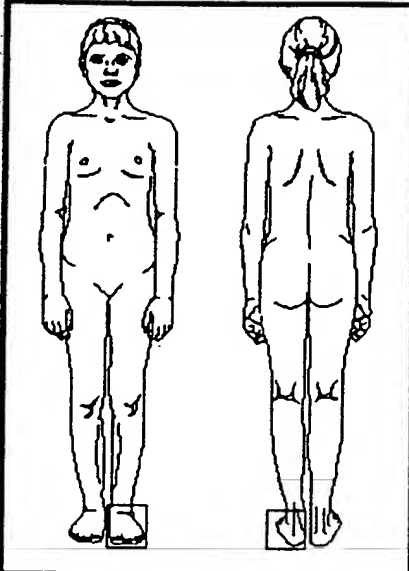
ROADWAY CHARACTERISTICS
Traffic Controls
Type of Trafficway
Traffic Flow
Type of Surface
Vehicle Action
Fixed Object Struck
Location of Fixed Object
Struck if Applicable
Surface Conditions (up to two)
Vision Obscured

Sample from the AMS Mobile Accident Reporting System

4.10.12 Drawings


Diagrams and graphics will be used where applicable to assist the coordinator in the data entry process. In the following sample, an anatomical diagram is available for a social worker to "drag-and-drop" pre-defined injuries to the specific areas of the body.


Injury Types Mike Fitzurka



Injury Type
Bite
Bruise
Burn/Scald
Concussion
Dislocation
Fractured Bone
Internal Injury
Laceration
Puncture Wound
Sprain
Subdural Hematoma

Body Part	Injury Type
Head	Concussion
Left Foot	Sprain
Left Leg (above knee)	Laceration


Delete


Note

Sample Screen from the AMS Child Welfare System

4.10.13 Narrative Information

The Narrative Information field allows the user to enter large sections of text. This tool is used throughout the application wherever text must be entered.

Sample from the AMS Mobile Accident Reporting System

4.10.13.1 Pre-defined Reports

The user will be able to print the standard organ donor information forms from Vitalink. All reports can be viewed and analyzed on the computer system before printing occurs.

4.10.14 Utilities

Several useful tools have been included in the Vitalink prototype to aide the coordinator in gathering information at the donor site. A standard alarm clock/stopwatch and a calculator are included in the application. The operation and application of these utilities are described in the following paragraphs.

4.10.14.1 Alarm Clock/Stopwatch

An alarm clock/stopwatch function, located at the bottom of the screen on the Status Bar, will allow the coordinator to measure the length of time spent at an donor site or the length of time needed for filling out the report. The alarm clock can also be set to denote specific times for meetings or deadlines.

4.10.14.2 Calculator

A calculator function can be accessed at any time. It can be set to display in normal or scientific mode.

4.10.14.3 Change Password

The system will prompt for a new password when an authorized user logs in for the first time. The selected password should be easy to remember but not easily guessed by others (i.e. birth date or name). This confidential password is used every time the user logs into the system to insure security of the system's data files.

4.10.14.4 Pen Settings

The user can configure the settings for the pen with this option. Settings like ink width and double tap are useful for tailoring the Vitalink to individual users.

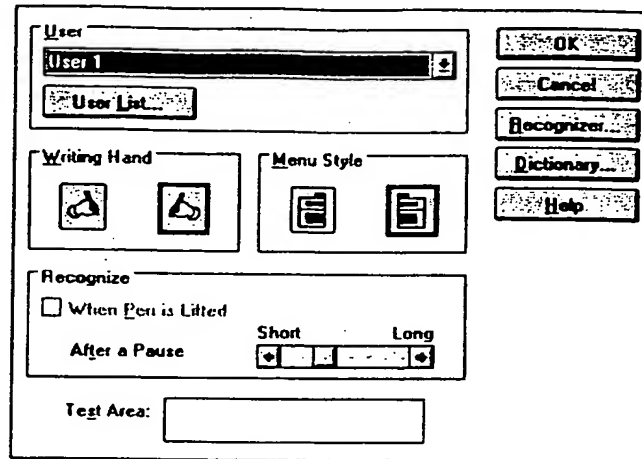
The screenshot shows a 'Pen Settings' menu with the following sections:

- Pen Ink**
 - Ink Width:** A slider between '0' and 'A'.
 - Sample:** A box containing a horizontal line.
 - Ink Color:** A grid of 16 color swatches.
- Pen Double-tap**
 - Double-tap Area:** A slider between 'Small' and 'Large'.
 - Double-tap Speed:** A slider between 'Slow' and 'Fast'.
 - TEST:** A button.
- Press and Hold Time Delay:** A slider between 'Short' and 'Long'.
- Try writing and selecting here:** A text input field containing 'Sample Text'.

At the bottom are four buttons: **OK**, **Cancel**, **Configure**, and **Help**.

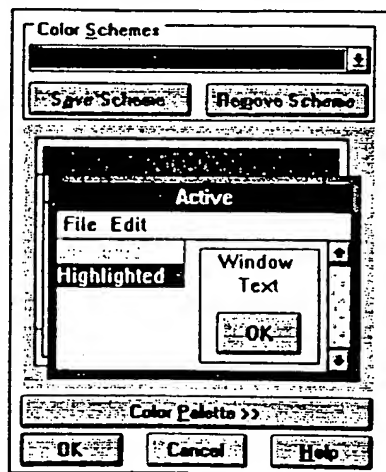
4.10.14.5 Handwriting Settings

The handwriting settings can be customized with this option. Each user can create a unique profile that allows a character dictionary to be built over time. This character dictionary will enable improved recognition in parts of Vitalink that use character input. In addition, a handwriting property can be set here to enable recognition patterns for right and left handed writers.



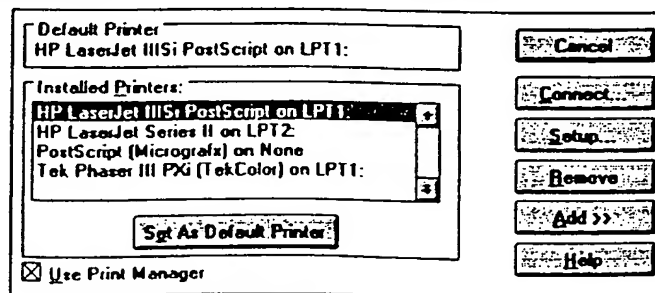
4.10.14.6 Color Settings

Color settings can be optimized by individual users. Even though the Vitalink application may be operating only on a black and white screen, these changes can improve visibility for different lighting conditions.



4.10.14.7 Printer Settings

Printer settings can be modified using this configuration option.



4.10.15 Additional Applications

The Vitalink software will allow other applications to be accessed through the Window menu item. In the future, other software packages, for example a word processing application or other automated administrative forms, can be added to contribute to Vitalink. This screen illustrates how new applications are added.

Description:	<input type="text"/>	<input type="button" value="OK"/>
Command Line:	<input type="text"/>	<input type="button" value="Cancel"/>
Working Directory:	<input type="text"/>	<input type="button" value="Browse..."/>
Shortcut Key:	<input type="text" value="None"/>	<input type="button" value="Change Icon..."/>
<input type="checkbox"/> Run Minimized		<input type="button" value="Help"/>

4.10.16 Help

Help will be available at all times in the Vitalink application by touching the various help icons. The user will be able to easily search on various help topics throughout the system. The Help function will be modeled after standard Windows help facilities.

5. TECHNICAL ARCHITECTURE

5.1 Mobile Computers

This section describes the technical components of Vitalink. The software and hardware requirements are based on proven hardware platforms and available software development tools. The Vitalink concept, design, and databases will be portable to all types of computer hardware that are compatible with the Intel 386/486 processor and Microsoft Windows for Pen Computing.

Vitalink is designed to run initially on the Fujitsu 325Point. The 325Point is a light-weight, hand held, pen-based computer. It is 8.7" x 11.7" x 1.16", 3 pounds, and uses a 386SL microprocessor. There are no external wires or attachments to restrict the user in any way. This type of portability is extremely helpful to mobile professionals that may not be able to remain stationary while collecting data. The Fujitsu 325Point specifications are included in the Appendix.

It is important to reiterate that this application is designed to run on all pen-based computers that are designed to use the Microsoft Windows for Pen Computing interface. The Fujitsu product is just one example of the technology available. Listed below are some of the other pen-based platforms that AMS supports with the Vitalink software:

Manufacturer	Model
NEC	Ultralite VERSA (Pen-Based)
	VERSA Pad
AST	Convertible 386/486
	GRiDPAD sl
Toshiba	T100X

5.2 Host Workstation Components

The host application will run on an MS-DOS or OS/2 workstation. UNOS will require at least one computer to act as the host workstation with the following minimum hardware and software requirements:

Workstation Hardware	Software	Peripherals
Intel 486/66 MHz processor	MS-DOS 6.0 or OS/2	HP LaserJet-compatible Printer
16 MB RAM	MS Windows for Pen	14.4kbps Data Modem
500MB hard drive	MS Access	
3 1/2" floppy drive		
5 1/4" floppy drive		

5.3 Mobile Data Communications

Today, many organizations need a communications system to extend their internal computer system to their mobile work force. This system must transmit

information to the mobile user efficiently, accurately, quickly and reliably with a minimum of human intervention.

The primary objective of the mobile communications user is to send and receive messages and data from anywhere at anytime. Systems capable of doing this must be simple to operate. They must handle the receiving, routing, and store and forward message delivery, regardless of the recipient's location. A user should have to know only a recipient's address, not their location.

There are two primary options for wide-area wireless data communications. Existing cellular systems can support fax and data transmission. These networks were designed primarily for voice transmission and are not optimized for data communications. Some regional carriers have begun reconfiguration of their cellular networks to support reliable, digital data communications. This new layer will be optimized for mobile data communications. United Parcel Service (UPS) is the largest user of cellular technology for data communications today.

5.3.1 Cellular Data

The reconfiguration of the nation's cellular networks to support digital data transmission makes cellular technology relevant for the UNOS Vitalink application. We are incorporating cellular data communications in the prototype release scheduled for February, 1994.

Cellular data communications is based on the asynchronous, or serial, connection protocols many are familiar with using direct connection or wired modems to communicate. The difference is the modem is connected to a device that can communicate via cellular network. Many phone manufacturers offer phone models that have a data port and modem.

The existing cellular networks are configured for voice communications. This presents some limitations for passing data over these networks. The primary weakness of cellular is the data integrity and error checking. A voice user of cellular doesn't blink an eye when the voice signal weakens or is lost altogether. However, a weak or lost connection in a data transaction is fatal. The error checking necessary to ensure a byte arrived correctly slows down data transmission.

Most network providers (Regional Bells, Cellular One, Meritech, GTE, PacTel, etc.) are adding a digital layer to their existing cellular networks to support digital data communications. This will support massive data communications with the added integrity of error checking of the digital (1 or 0) signal. Cellular data networks with digital capability are in testing in some metropolitan areas already, and will be common by 1996.

5.3.2 RAM Mobile Data

RAM Mobile Data is the only provider of packet-switched, wireless data communication services committed solely to providing such services.¹ RAM is

¹ Information from RAM Mobile Data System Overview, Release 4.1, September 30, 1993, Copyright 1993 RAM Mobile Data USA Limited Partnership

not affiliated with any particular equipment vendor and is committed to providing its customers with the appropriate equipment, application software and connectivity tools at the best possible prices. RAM supports the development of specialized equipment and software based on the open MOBITEK protocol. RAM is the only company to offer a proven, nationwide system that offers all the features demanded in today's wireless marketplace. These features are essential to support a full array of horizontal and vertical market applications. These features are:

- Wide coverage
- Seamless roaming
- Store and forward capability
- Excellent response times
- Virtually unlimited capacity

To operate on the RAM MOBITEK networks, RAM customers need radio modems and terminals designed to operate with a MOBITEK system. RAM provides documented open interfaces that enable development of custom application software and system integration services. Radio modems and terminal equipment are available directly from manufacturers to RAM customers. RAM ensures system compatibility by testing and certifying all products for use on its networks.

5.3.3 Packet Switching

Packet switching offers the most efficient way to transfer data. In packet switching, no end-to-end network connection is established. Instead, a packet of data is transferred between nodes until it reaches its final destination (the previously used facility is now free to handle another packet). In circuit switching, an end-to-end network connection must be established before data transfer can start. This method ties up the entire circuit, and no other data can be sent until the first transmission is completed. The radio path and other facilities may not be used even during idle time between user messages. Most voice messaging carried out between offices and mobile units can easily be replaced by packet data messaging.

5.3.4 MOBITEK

MOBITEK is a trunked, terrestrial, mobile radio system for packet-switched data traffic used for a variety of applications. The original concept for MOBITEK mobile radio communications was the design of a mobile alarm system used by field personnel of Swedish Telecom Radio. Because the concept was not economically feasible as a private network, it evolved into a public mobile radio service, which became MOBITEK.

Early development of the MOBITEK network was carried out by Swedish Telecom. Continuing development is being carried out by Eritel, a joint venture Swedish Telecom and L.M. Ericsson. Ericsson is a manufacturer of MOBITEK network and mobile equipment. MOBITEK was first placed into commercial

operation in Sweden in the fall of 1986. Networks have since been constructed in Norway, Finland, the United States, the UK, the Netherlands and Canada. Additional MOBITEK networks are currently being installed in France and Australia, and many others are planned.

Current MOBITEK systems comprise radio base stations, local switches, regional switches, and a network control center. They are trunked radio systems, meaning the radio channels are a common resource shared by all the users. Unlike trunked radio systems, traditional private radio systems have dedicated radio channels.

MOBITEK subscribers communicate with others individually or as groups. Communication is also possible between MOBITEK subscribers and other external networks connected to the MOBITEK system.

RAM Mobile Data selected MOBITEK for its mobile data communications networks because of MOBITEK's proven efficiency, reliability and flexibility to meet the many requirements of individual business and government users. MOBITEK is a worldwide standard for packet switched wireless data communications.

Worldwide standardization of all MOBITEK networks and the compatibility of future development of advanced network features and functions are ensured by the MOBITEK Operator's Association (MOA). MOA is an independent organization of all network operators who offer wireless data service, using the MOBITEK standards.

5.3.5 Non-proprietary

Descriptions of the MOBITEK operating protocols for radio modem hardware and software are open and available, without license fees, to any vendor planning to produce MOBITEK compatible equipment and applications. Copies of the MOBITEK Interface Specification (MIS), which details the open protocols, are available from RAM at a nominal cost.

The RAM MOBITEK system support many open interfaces such as TCP/IP, LU2, X.25, POS and AT. Other interfaces will be added to meet market demands.

5.3.6 RAM'S MOBITEK System

RAM has operating licenses for its US MOBITEK networks in more than 200 markets, including MSAs (Metropolitan Statistical Areas) and RSAs (Rural Statistical Areas). RAM's system now services over 6000 cities and towns in the US, covering over 90% of the urban business population. Additional coverage will be added in the future. RAM also provides MOBITEK service for the UK.

5.3.7 Canada

Cantel is operating a MOBITEK network in Canada in the same radio frequency band as that used by the US. Customers can connect to either system, using the same radio modem, provided they have subscriptions on both. This is called cross-border roaming.

5.3.8 RAM Network Features

MOBITEX networks incorporate a number of key features that distinguish RAM networks from other mobile data networks. The following table shows a summary of these features, along with the benefits to RAM's customers.

- | | |
|---|--|
| • Trunked radio frequency design and channelization | • High capacity |
| | • Immediate channel availability |
| | • Long-term growth without congestion |
| • Intelligent base stations and automatic Registration | • High reliability and efficiency |
| | • Smoother outbound messaging |
| | • Automatic roaming |
| • High data rate, low overhead | • Higher capacity |
| | • Greater throughput |
| | • Quicker response times |
| | • More sophisticated applications |
| • Greater depth and breadth of coverage | • More applications for hand-held terminals |
| | • Local, regional, national and international applications |
| | • Volume equipment purchase |
| | • Single-source service provider |
| • Non-proprietary over-the-air protocol | • Competitive bidding among vendors |
| | • Customized hardware and software |
| • Data-only, packet-switched networks | • Reliability |
| | • Security |
| | • Cost effectiveness |
| • Personal subscriptions | • Security |
| | • Personal identification |
| • Expert network operations and maintenance | • Around the clock network monitoring |

5.3.9 Subscription Types

A subscription is required for anyone communicating on RAM's MOBITEX system. Subscription types vary and are based on the system services chosen and on where and how the customer wants to use the network.

RAM's MOBITEK system offers the following subscription types:

- Host Terminal subscription
- Mobile subscription
- Personal subscription
- Group subscription

Various system services can be linked to each of these subscription types.

Access security can be implemented through the use of personal subscriptions with password protection, and through closed user groups that limit communications to a specified list of subscriptions. Additional levels of security can be provided in a subscriber's application.

Subscription information and services are stored in network nodes and the terminal itself. This information is divided into two types: fixed and variable. The fixed subscription information is stored in the network and includes:

- The definition of subscription and services
 - Subscription type
 - Subscription number
 - Group numbers
- Password
- ESN
- Technical data about terminal equipment
 - Radio frequencies
 - Terminal type

The subscription information is registered in the NCC when a new subscription is ordered by the customer or a subscription is changed.

Variable subscription information is stored in all the network nodes and includes:

- Roaming information for traffic routing
- Message sequence numbers
- Subscriber status
- Active personal subscriptions

5.3.9.1 Host Terminal Subscription

A host terminal subscription is always linked to a particular terminal (generally a PC or host) connected to RAM's MOBITEK system through an FEP to a local switch.

Host access to the system is usually provided by FEPs connected to the system at the local switch level. In addition, the FEP supports protocol conversion.

Currently supported is a datagram-to-session gateway for X.25 and SNA/3270, and a datagram-to-datagram gateway for TCP/IP.

5.3.9.2 Mobile Subscription

A mobile subscription is always linked to a particular radio modem. Radio modems communicate with the RAM MOBITEK system through radio links to the base stations.

Any type of peripheral equipment (e.g., PCs, printers or simple terminals) can be connected to a radio modem through RS232 or specialized interfaces. Radio modems can be integrated with portable terminals and PCs, as well as terminal equipment designed for installation in vehicles.

5.3.9.3 Personal Subscriptions

A personal subscription is linked to a person and not to a particular terminal. It can be activated from any host, portable or mobile terminal that supports personal subscriptions. This flexibility is useful for customers who often use terminals located in more than one location.

Any system services defined in a personal subscription are available when the user logs onto the network. However, the technical limitations of the terminal being used can limit their services.

A login message sent from the terminal includes a password. It also notifies the MOBITEK system that a personal subscription is being logged in and the address of the terminal being used. The MOBITEK system considers the subscription transferred to this terminal until the user sends a logout message or logs in at another terminal. A personal subscription can only be logged in on one terminal at a time. A terminal can have up to seven personal subscriptions logged in simultaneously.

A password is mandatory for personal subscriptions, and protects the subscriber from unauthorized use. To increase the level of security, the subscriber can request the network operator to change the password at the NCC.

5.3.9.4 Group Subscriptions

A group subscription comprises a number of mobile and host terminal subscriptions. Each mobile or host subscription can be a member of up to 15 different groups. The members of a group are addressed by the subscription number of the group. A group subscription only receives messages.

This service minimizes the work of dispatch personnel by sending identical messages to numerous subscriptions. A group message is sent to terminals in a limited geographical area, selected by the customer. This area is defined by a selected set of base stations together with the host terminals for the group. The base stations and host terminals are designated as search nodes.

There is no definite acknowledgment from each recipient of a group message. Any unit that is out of radio range, shadowed or switched off will not receive the message. However, the network will broadcast a group message several times.

The group subscription information contains a definition of:

- Mobile terminal subscriptions
- Search area
- Traffic type (data, text or status)

5.3.10 Messaging Services

Messages delivered through the RAM MOBITEK system are sent MPAKs. An MPAK contains from one to 512 bytes of user information. A 1-byte message is called a status message. Longer messages, containing up to 512 bytes of user information, are sent in ASCII text format or as data coded in any application-dependent format. The maximum size of a text message is 545 bytes (512 bytes of user data and 33 bytes of network data).

Sets of 256 numerically encoded status message codes allow many standard messages to be sent quickly and economically through the system.

More complex digital information is sent as

- Data
- Higher Protocol Data (HP Data are sub-messages of messages longer than 512 bytes)

The following table shows the types of services available to subscribers on the RAM MOBITEK system.

Services	Mobile	Fixed	Personal	Group
Text/Data/HP Data	✓	✓	✓	✓
Status	✓	✓	✓	✓
Password			✓	
Group Messages	✓	✓		
Store and Forward	✓	✓	✓	

5.3.10.1 Text Messages

Text messages consist of MPAK header information and user-supplied data coded according to international ASCII standards. The maximum size of the user data in a text message is 512 characters (bytes).

5.3.10.2 Data Messages

Data messages consist of MPAK header information and user-supplied data. Data messages are used instead of text messages when information is transferred in formats other than ASCII. In contrast to text messages, user data can be freely coded by the individual terminal application. The maximum size of the user data is 512 bytes.

5.3.10.3 HP Data

HP Data (Higher Protocol Data) is used for messages that exceed the maximum size (512 bytes) and indicates that the contents of the associated packet require special processing. In the transport layer (included in the user application), the original message is disassembled into several sub-messages (multiple MPAKs). These sub-messages are then transmitted as HP Data messages by the network layer.

The receiving terminal's transport layer protocol reassembles the sub-messages into the original complete message. The order in which the different sub-messages are transferred to the receiving terminal is not controlled by the MOBITEK system.

HP Data messages are divided as follows:

- MPAK Header information
- Type of protocol used in the transport layer
- Transferred user information

5.3.10.4 Store and Forward

A store-and-forward capability is available for subscribers who are temporarily out of contact with the system when messages are sent to them.

If the addressee of a MOBITEK message cannot be reached the message is temporarily stored in the system. A copy of the message, and an acknowledgment indicating that the message has been stored in an electronic store-and-forward device, are returned to the sender. Before the message is sent, the sender may choose not to use the store-and-forward capability.

When the addressee of a stored message re-establishes network contact and is registered, stored messages are sent. The addressee is informed that the messages received were stored in the electronic store-and-forward device.

The store-and-forward device has capacity of ten messages per subscription. Once a mailbox is full, new messages are returned to the sender. Messages not retrieved within several hours are deleted.

5.3.11 MOBITEK Functions

The RAM MOBITEK system incorporates many unique functions to provide a seamless, transparent communications link for its customers. These functions also enable RAM to achieve its primary goals of:

- Maximizing radio path efficiency to ensure economical service
- Providing effective traffic routing
- Providing a fast and reliable mobile data communications service
- Making superior services available to all users, regardless of subscription type
- Maximizing customer satisfaction

Traffic congestion in most wireless communication systems occurs primarily in the radio link. One way to minimize traffic congestion is to reduce the number of packets transmitted through the base station. There are several ways to do this.

First, the system makes no attempt to reach terminals out of network contact (i.e., equipment is switched off or out of radio coverage). The store and forward service is provided to handle these cases.

When terminals are switched off, they notify the system by sending an inactive message. All the personal subscriptions registered on that terminal will also become inactive.

When terminals are switched on, they automatically notify the system by sending an active message to the base station. The system maintains a log of active terminals and their locations. Host terminals send an active message immediately after being switched on. Mobile terminals can be set to delay the transmission of the active signal. Only if a mobile terminal is inactive within a set delay time of 30 to 60 seconds will an active message be automatically sent to the base station. The purpose of this delay is to avoid unnecessary traffic on the radio channels.

If a mobile terminal loses radio contact with the system, it automatically sends an active message when radio contact is re-established (subject to the above mentioned delays). Messages that have been stored in the subscription's store-and-forward device are then sent to the mobile terminal.

A second method that helps to reduce congestion makes use of a distribution list that enables a single message to be sent to a number of other subscribers. The sender includes the MANs of all the addressees when sending the message. The system copies and transfers the message to each of the addressees. A group broadcast message may also be sent to a number of subscribers sharing a single subscription number.

To keep the transfer time for messages between subscribers as short as possible, all traffic is processed through a minimum number of system nodes. The hierarchical structure of the MOBITEK system, together with the storage of subscription information in the current system branch ensures efficient routing of messages.

When a message is sent between two subscribers operating through the same base station, it will be processed by that base station only. In this case, the base station is designated as the turn-around node for the message. If subscribers are using two different base stations connected to the same local switch, the local switch is the turn around node for the message. If a regional switch is

involved in the traffic routing of a message, it is the turn around node for the message.

5.3.11.1 Reliability

To make communications more reliable, network nodes can function in autonomous operation if the connections to superior nodes are lost.

When a base station is in autonomous operation, traffic between mobiles registered at that base station can continue. Likewise, if a local switch is in autonomous operation, all traffic between base stations connected to that local switch can continue. This method of operation guarantees that any temporary link failure in the system will have minimum impact on service. Dial-up modems can also establish temporary connections between nodes in case the main connection is lost.

5.3.11.2 Roaming

Roaming provides mobile radio modems (mobiles) with the ability to stay in constant communication with the system. Mobiles monitor and evaluate system channels from surrounding base stations. An algorithm built into the radio modem determines if and when transfer to another base station is necessary.

When a mobile terminal moves to a new base station, it sends a signal to the new base station to inform the system that all subsequent traffic to this mobile terminal should now be routed through the new base station. Subscription information stored in the old base station is forwarded to the new base station and other nodes within the new network branch. Current system channel and current base information, stored in the radio modem's memory, is updated when the radio modem is powered off.

5.3.12 System Performance and Reliability

Performance of the system can be measured in terms of the time it takes to transfer a message between a mobile radio unit and an attached host (or another mobile) anywhere in the system.

This measure is dependent on the system configuration, including radio channel parameters and the following:

- Message length distribution
- Baud rate of internode links
- Node processing time
- Number of nodes involved
- Overall traffic load

Average one-way message transfer time through the RAM MOBITEK system ranges from two to five seconds, depending mostly on message length and the number of nodes involved. At least 90 percent of all messages to active subscribers in good radio contact are delivered within ten seconds.

The design of MOBITECH includes very few components that can fail and cause a total system failure. For example, the loss of a radio channel in a base station would only be evident as a reduction in the service level for the base.

All communication links between nodes in the RAM MOBITECH system are backed up to rapidly restore service in the event of failure, and all communications equipment is centrally monitored as part of RAM's MOBITECH network management system. If the connection between two network nodes is lost, the node on the lower level will go into autonomous operation, and the next higher node will send an alarm to the Network Control Center (NCC) reporting this event.

The RAM MOBITECH system includes spare local switches for scheduled maintenance and for backup in case of a node failure.

Long-distance providers (LDPs) likewise have spare switches to minimize any loss of cross-region traffic should a switch fail. Also, customers may elect to connect their hosts directly to multiple local switches (where traffic patterns warrant) to obtain additional redundancy in their overall network solution. Temporary base station failures are generally not serious because of area containment and the overlap by adjacent base stations.

RAM Mobile Data's objective is to maintain an overall system availability of 99.9% or better. To achieve this, RAM will ensure the following:

Base Stations

- 90 percent will be repaired in four hours or less
- Traffic-affecting alarms will be:
 - Escalated to a field engineer immediately
 - Escalated to the director in four hours
 - Escalated to the network vice president in eight hours

Switches

- 90 percent will be repaired in two hours or less
- Traffic-affecting alarms will be:
 - Escalated to a field engineer immediately
 - Escalated to the director in one hour
 - Escalated to the network vice president in two hours

6. PROJECTED COST

This section lists the estimated hardware, software and communications costs for implementing the full Vitalink application. Additional development costs for the custom Vitalink application are not included here.

Host Costs

Host workstation computer: \$4,500

(including radio modem)

Connectivity \$100 per month

Per User Costs for RAM Implementation

Mobile computer: \$2,000

Radio Modem \$775

Service Charge \$25 per month

Transaction Cost \$0.125 Cents per 512 characters

Average transaction size 1024 (min.) - 10,240 (max.)

Average transaction cost \$0.25 - \$2.50

Per User Costs for Cellular Data

Mobile Computer \$2,000

Cellular Phone & Modem \$800

Monthly Service Charge \$13.95

Transaction Cost \$2.00 - \$5.00 avg. per transaction (projected)

7. SCHEDULE

7.1 Prototype Development

This section describes the system development plan and the prototype release schedule. The Vitalink system development plan is based on AMS's Rapid Development Methodology. This methodology is a subset of AMS's Lifecycle Productivity System (LPS), which is a set of corporate-wide tools and standards for developing quality software.

User Interface, Application Functions and General System Design

In this phase, the AOPO form will be broken out into a comprehensive yet easy to use interface. The functions of the system will be dictated by the amount and types of information uncovered during this phase. A general system design for the wireless communication process will also be outline during this phase.

MILESTONE DATE: December 20, 1993

Vitalink Initial Prototype Release 0.1a

The initial release of the Vitalink prototype is intended to provide UNOS and the pilot Organ Procurement Coordinators an introduction to pen-based computing and help them understand the user interface. Advanced features are not supported and communications are not included in this release.

MILESTONE DATE: January 5, 1994

Vitalink Prototype Release 1.0

This release of the Vitalink prototype will include identified enhancements to the user interface and the wireless communications. This release will be used for the prototype test at the chosen test sites.

MILESTONE DATE: January 31, 1994

7.2 Prototype Feedback

This phase will monitor the operational test sites and gather feedback data to develop a proof-of-concept document. The analysis results from this stage will be used to develop the production version of Vitalink. This phase has not yet been tasked.

DATE: February - April, 1994

7.3 Production Development

A plan for production development and implementation will be developed based on the results of the feedback from the Vitalink prototype. User interface enhancements, communications, and back-up methods will be tuned and polished for a production version of Vitalink to be released. This phase has not yet been tasked.

DATE: July, 1994

UNOS **VITAL LINK**

Pilot Overview and Training Guide

February, 1994

UNOS United Network
for Organ Sharing

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1. INTRODUCTION

The purpose of this document is to set expectations and requirements for the participants of the Vitalink pilot. The purpose of a Pilot Evaluation is explained as well as the basic functionality of the Vitalink system.

The goal of the Vitalink prototype is to accomplish the implementation of baseline functionality first, and add on more sophisticated functionality when feedback from the users can be analyzed and evaluated. This type of iterative design and development process is proven to be very effective in creating an accurate design and developing a better overall system.

2. BACKGROUND

Vitalink is a data collection tool designed for the unique requirements of the organ sharing community. It is application software combined with pen-based, hand-held computers and wireless data communications. Vitalink supports Organ Procurement Coordinators in the field to collect and transmit the essential donor information to the UNOS Organ Center so that a match run can be executed on the existing system at UNOS. Vitalink provides a mechanism to standardize the data collected about donors to increase the chance of organ placement. Vitalink allows the coordinators to collect the donor data wherever and whenever the information becomes available.

Vitalink automates the data on the Association of Organ Procurement Organization's (AOPO) form. The appendix illustrates how the AOPO form was broken out for the Vitalink system. The user interface for the mobile portion of Vitalink was delivered on January 10, 1994. The wireless communications will be incorporated by the end of March for prototype delivery. Full-scale implementation is planned for late summer of 1994 after a thorough review of the prototype results.

Originally established in 1977 by members of the South-Eastern Organ Procurement Foundation (SEOPF), the United Network for Organ Sharing (UNOS) operates the national Organ Procurement and Transplantation Network (OPTN) and the national Scientific Registry for Organ Transplantation. In this role, UNOS functions as a contractor for the federal government and a private, non-profit corporation. Under contract with Health Resources and Services Administration (HRSA), UNOS has operated the OPTN since September 30, 1986, and the Scientific Registry since September 30, 1987.

American Management Systems, Inc. (AMS) is the developer of the Vitalink Application software in partnership with UNOS. AMS is based in Fairfax, Virginia. Founded in 1970, AMS specializes in helping clients improve their performance through the intelligent use of information technology. AMS combines specific industry experience, business function expertise, proven systems development practices, and an extraordinary depth of technological competence to help our clients meet their business goals.

3. VITALINK LIFECYCLE

The successful use of any resource occurs through a lifecycle beginning with requirements identification and ending with disposal. Traditionally, information technology solutions are developed using a lifecycle approach beginning with a requirements study that results in the design, development, maintenance and ultimate disposal of an information system. Disposal usually is preceded by a new lifecycle for the application's replacement.

Many information technology applications, like accounting, payroll and inventory systems, are known well enough to be implemented using a traditional approach. Often, the core functions of these types of systems are assessed using a binary measurement - either they work or they do not. The traditional lifecycle is best suited to stable, institutionalized processes.

On the other hand, advanced technology applications can be very costly and fall short of their functional goals when using a traditional approach. An iterative and practical approach is more appropriate for mission-critical advanced technology projects. The iterative approach uses a series of development cycles - design, develop, test - to achieve functional goals. Each iteration serves as a checkpoint to measure progress and solve application problems.

3.1 A Risk-Based View

A risk-based view of the enterprise solution is effective for developing an iterative development plan. The iterative plan addresses each risk area and identifies the factors or approaches that mitigate the risks or minimize the adverse impact of problems stemming from a risk.

Risk is the likelihood of injury or harm. A practical measurement of risk is the probability times the severity of something occurring. The risks typically encountered in an advanced information technology application are listed below.

3.1.1 Concept Risk

Acceptance and Continued use

Concept risk can encompass aspects of all of the risk areas below. Problems at the concept level will reduce system acceptance and continued use. New processes, technologies, users and design principles affect the feasibility of the solution concept and its long-term success.

3.1.2 Economic Risk

Potential for other outcomes:

Revenue, direct or indirect savings, and support-cost projections

Financial planning for a technology solution includes estimating lifecycle costs and benefits of a system during its lifecycle. Economic risks are the factors that cause the project to fall short of revenue, savings or support-cost projections.

Iterative prototyping helps alleviate economic risks by enabling the development of accurate financial models based on each application release. These models can be more accurate each time as the sample increases and the quality of the application improved.

Support is usually the most costly part of the system lifecycle. Emphasis on a well-conceived support plan will prepare the organization for economic risks.

3.1.3 Technology Risk

New or Unproven for use, users, volumes and performance requirements

Technology risks grow when there is a mismatch between the requirements and the technology specifications and performance. Technology planning based on high-medium-low expectation scenarios of the system's performance can avoid problems in this area. The significant difference between development, prototyping and production is the amount of user demand on the system. Each component of the system should be designed to support maximum loads independent of other components.

These factors include handwriting recognition accuracy of pen computers, durability of field devices, battery life and communications. For example, poor communications throughput puts additional demand on system battery and ultimately affects overall system performance.

3.1.4 Implementation Risk

Software design, project management, integration and delivery

Implementation problems affect long-term project success through missed deadlines and component integration problems. Key problem areas during implementation are access to reliable development resources, project planning, component integration and component obsolescence.

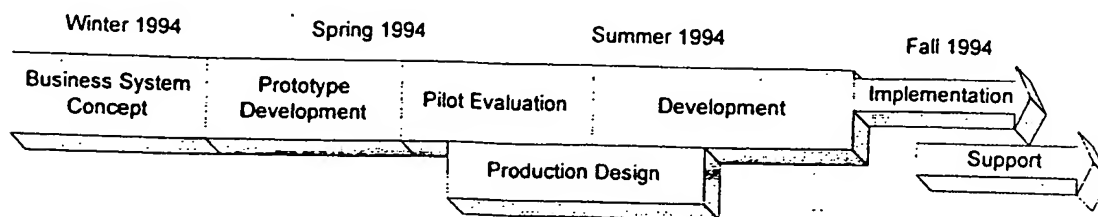
3.1.5 Organizational Risk

Traditions, norms, processes, culture, new skills

Organizational factors are the most challenging to solve in an information technology application. They are at the heart of the organization and they represent how the organization executes its mission. Changes in these areas can result in complex cause and effect reactions that are difficult to solve or mitigate.

Organizational risks usually range from inadequate developer skills, lack of management support, process redesign and low user acceptance. A change management plan that accounts for these organizational areas is effective for managing this area.

3.2 Project Phases



The Vitalink application is being developed using a phased approach. Seven overlapping phases are planned during the lifecycle of this system. Some tasks from these phases may be repeated to enhance the accuracy of the Vitalink design. The phase which is discussed in this document is the Pilot Evaluation.

3.3 Why conduct a pilot evaluation?

The Vitalink Pilot Phase is one phase in the application's lifecycle. Feedback is gathered during the pilot phase on the application's performance in each of the risk areas described above. The key is to find the success factors that justify continuing with the project, while solving and managing problem areas that affect progress. However, focusing on risk areas can be too reactive when building a long-term technology vision for Vitalink.

The key to the successful pilot evaluation is the measurement of the important attributes of the Vitalink application within the risk and business, technology factors structure. This will help to establish the plan for continuing. Many of these answers are known today. For example, wireless communications are consistent with UNOS strategy and systems architecture. A detailed Vitalink evaluation plan is developed in the next phase to support feedback gathering and future planning efforts.

4. PLAN FOR EVALUATION

4.1 Surveys

Both phone and mail surveys will be used throughout the life of the pilot in order to evaluate Vitalink's performance and usability. Participants in the pilot should expect phone calls at least one every two weeks to determine the progress of the system evaluation.

4.2 Site Visits

Follow-up site visits will occur at least once during the prototype. A simulation of the use of Vitalink and a group discussion between the coordinators will be used to collect information about the Vitalink system.

4.3 Telephone Support

The technical support phone line will be available to all users of the Vitalink system. Users can call to report problems, ask questions or even to give suggestions and ideas for improvements to the system.

5. CONSENT FOR PARTICIPATION

As a participant in the operational testing of Vitalink, you agree to provide to UNOS feedback on a regular basis on the performance of the Vitalink system. This pre-production version of Vitalink is not meant to replace the current donor information collection process. Instead, it is to be used in conjunction with the current process to identify the benefits and/or short comings of the Vitalink application. The input which you provide will be folded back into the production system development in order to make a donor information management tool which can be used effectively by every Organ-Procurement Coordinator in the field.

The Vitalink software has been developed to target approximately 80% of the total functionality. It is through the feedback from the pilot participants that the remaining essential 20% functionality be uncovered. You can also expect that there will be program "bugs" or errors in the Vitalink system. Uncovering these problems is another function of pilot participation.

By signing below, I agree to the following:

1. I will not load any other software on the hardware which is provided specifically for the Vitalink operational test.
2. I will report any technical or functional problems encountered with the Vitalink software as soon as possible.
3. I will ask questions as they arise about the application of functions in the Vitalink system.
4. I will respond to UNOS sponsored phone and mail surveys on a timely basis concerning the performance and evaluation of the Vitalink system.

Signature

Date

Print Name

Organization Name

6. HARDWARE

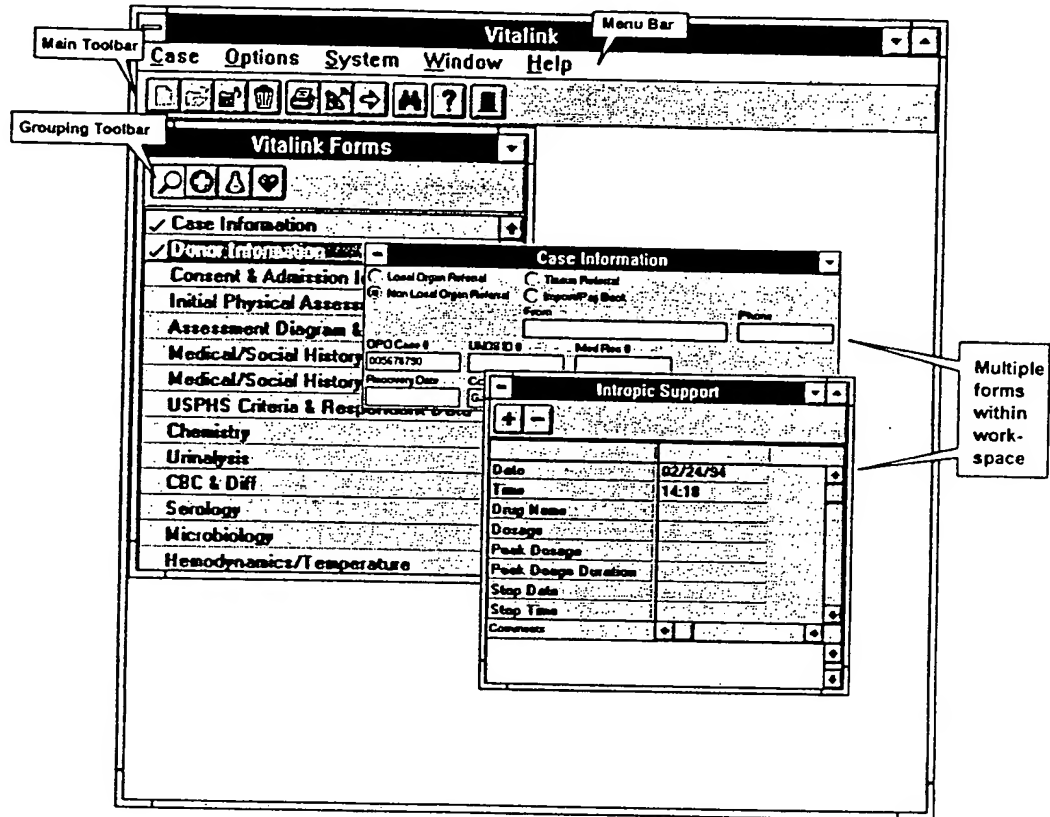
There are two types of hardware platforms being evaluated during the pilot. They are the Fujitsu 325Point pen-based tablet and the Compaq Concerto pen-based notebook. The Compaq is being demonstrated, but not supplied for the pilot. The following table lists the major attributes of each machine:

Machine	Processor	Hard Drive	PCMCIA	3.5" drive	Keyboard
325Point	386/25	42MB removable	1 Type II 1 Type III		✓
Compaq Concerto	486/25	120MB fixed	2 Type II	✓	✓

Each test site will also have a one Mobidem radio modem and one Lexmark/IBM portable printer. The radio modem only needs to be attached when sending data to UNOS. The printer only needs to be attached when printing the AOPO Vitalink report.

8. APPLICATION WORKSPACE

The Vitalink system is designed to be consistent with all standard Windows software. The illustration below shows a sample of the Vitalink application workspace.



Each part of the illustration above is explained in the following sections.

8.1 Main Menu

Case Options System Window Help

Each major function in Vitalink can be launched from the toolbar or the main menu. This is consistent with most Windows products. Touch the desired menu with the pen to access the menu choices.

8.1.1 Case Menu

<u>C</u> ase	<u>O</u> ptions	<u>S</u> ystem	<u>W</u> indow	<u>H</u> elp
	<u>C</u> lose			
	<u>D</u> elete			
	<u>P</u> rint			
	<u>S</u> end			
	<u>E</u> xport			
	<u>E</u> xit			

The actions listed above can be executed once a case is opened or created. The Case Menu controls specific functions concerning the current case. From the Case Menu cases are created, opened, closed, deleted, printed, exported, or sent to UNOS. Each of the options are discussed in more detail later in this document.

8.1.2 Options Menu

<u>C</u> ase	<u>O</u> ptions	<u>S</u> ystem	<u>W</u> indow	<u>H</u> elp
	<u>O</u> n Screen <u>K</u> eyboard			
	<u>P</u> opup boxed edit fields			
	<u>O</u> n top boxed edit fields			

The Options Menu allows the user to choose how to enter data when using the pen. No options should be selected if data entry is being performed via the attached keyboard. All of the edit boxes are illustrated in the Data Entry section.

On Screen Keyboard

Select the On Screen Keyboard option to have the soft QWERTY keyboard appear on top of the Vitalink application. This assists in data entry while using the pen. A check appears next to the name on the menu when this option is selected.

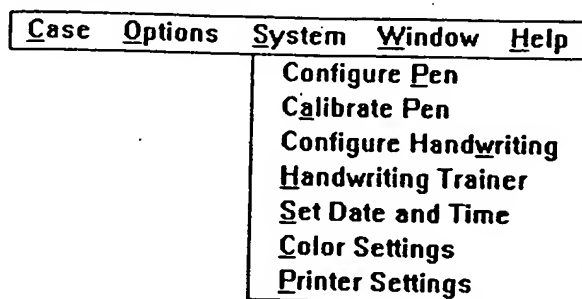
Popup Boxed Edit Fields

The Popup boxed edit fields option allows the user to write data with the pen in an expanded text box for easier character recognition. Each time the user touches a field when this option is selected, an edit box will appear to accept the written data. When a new case is created, this option is automatically selected. A check appears next to the name on the menu when this option is selected.

On Top Boxed Edit Fields

The On top boxed edit fields performs the same basic function as the regular popup boxed edit fields except that it always appears on top of the form and can be moved around by the user. A check appears next to the name on the menu when this option is selected.

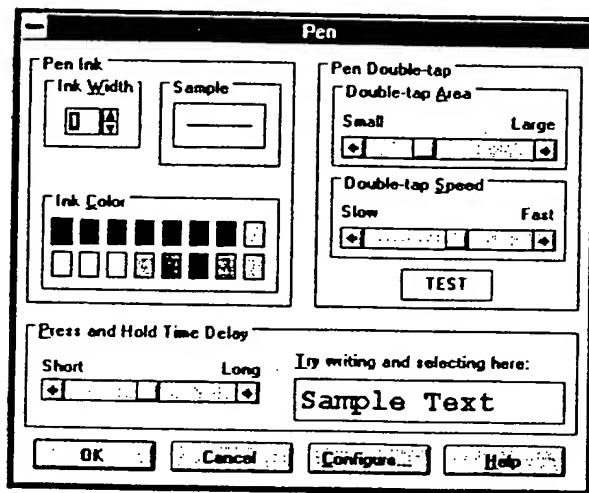
8.1.3 System Menu



The System Menu sets options specifically concerning system settings which affect Vitalink's look and feel. Each of the following options have on-line help available for a more in-depth discussion and assistance.

Configure Pen

The user can configure the settings for the pen with this option. Settings like ink width and double tap are useful for tailoring the Vitalink to individual users.



Calibrate Pen

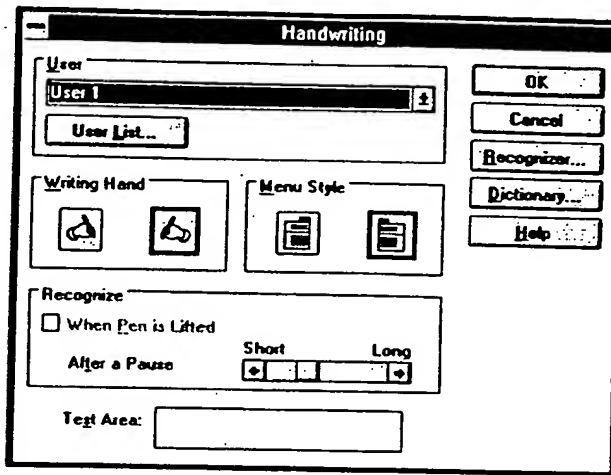
Occasionally the pointer on the screen becomes out of sync with where the pen is actually pointing. The calibrate pen function makes the user touch the cross point of two lines on various points of the screen. This should correct any pointing errors that may be occurring.



Configure Handwriting

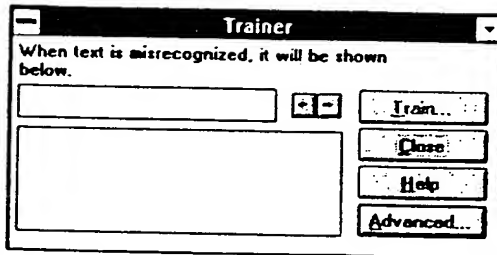
The handwriting settings can be customized with this option. Each user can create a unique profile that allows a character dictionary to be built over time. This character dictionary will enable improved recognition in parts of Vitalink that

use character input. In addition, a handwriting property can be set here to enable recognition patterns for right and left handed writers.



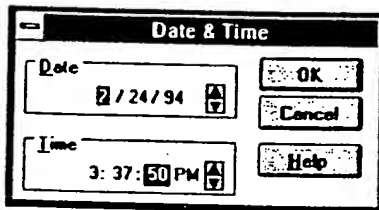
Handwriting Trainer

The handwriting training utility is a very useful tool to improve the overall character recognition of handwriting throughout the system. It is recommended that every user experiment with this function to become more familiar with the fundamentals of pen computing.



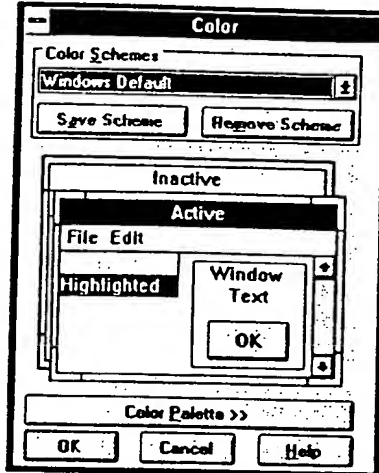
Set Date and Time

Occasionally the system date is incorrect when the battery runs down to extremely low levels. Use this function to correct the date and time.



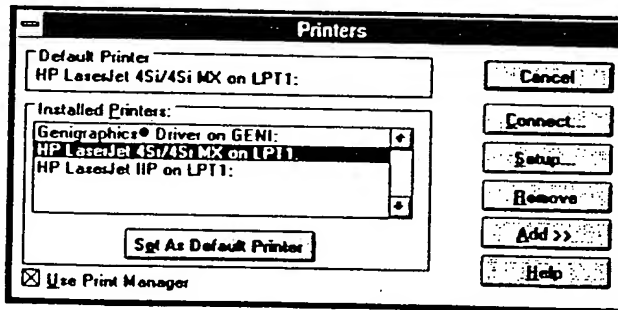
Color Settings

Color settings can be optimized by individual users. Even though the Vitalink application may be operating only on a black and white screen, these changes can improve visibility for different lighting conditions.

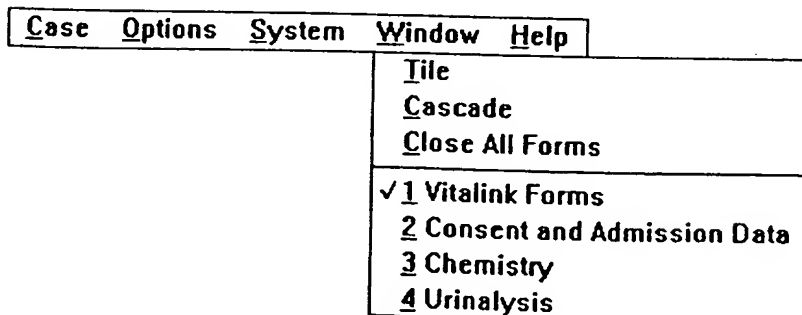


Printer Settings

Printer settings can be modified using this configuration option.



8.1.4 Window Menu



The Window Menu is used to manage your application workspace. The Tile and Cascade options allow the user to see all open forms in an organized manner. The Close All Forms option clears the application workspace of all open forms by

saving data and closing down each window. The Vitalink Form list window does not close while a case is still open.

8.1.5 Help Menu

Case Options System Window Help

There is no on-line help during the testing phase of Vitalink. The production on-line help will be similar to other Windows applications' on-line help. Vitalink's on-line help will closely following the User Manual which will accompany each licensed version of Vitalink.

8.2 Main Toolbar



Vitalink's main toolbar has an icon to represent each major function of the system. All of the functions available on the toolbar are also available through the menus.

8.2.1 New



The blank sheet of paper represents a new case. Press this icon when opening a new donor case.

8.2.2 Open



The open folder represents opening a case which already exists. Press this icon to get the following window:

Open Case		
Donor Name	OPO Case Number	Recovery Date
Larry W. Bender	0055787301	
Kathy Perretti	0045300121	2/1/94
Linda Meyer	0034388012	2/3/94
Mike Jones	00456733001	2/8/94

OK Cancel

Sort Order

Donor Name

OPO Case #

Recovery Date

Vitalink ID

UNOS ID

Donor Hospital

Medical Rec #

The Open Case windows allows the user to choose which order to view case information. To change the sort order, touch the name of the field which you want to sort on and drag it to the desired sorting position. This option gives the

coordinators greater flexibility in creating a customized interface. The sort order for opening a case can be changed at any time.

To open a case, double tap on the desired case, or touch the case and then touch OK.

8.2.3 Close



The closed folder represents closing an active case. Touch the close icon when a case is completed, or if you want edit or create a new case.

8.2.4 Delete



The trash can represents the delete function. Touch this icon when you want to delete the current case.

8.2.5 Print



The printer represents the printing utility. Touch this icon when you are ready to print the entire AOPO form. During the initial testing phase, only the entire report will be able to be printed. Eventually, different sections of the form will be able to be printed separately.

It will take several minutes to print the entire AOPO Vitalink form. Vitalink calls Microsoft Word for Windows to perform the reporting function and display the report on screen. Touch the print icon in Word to print to the printer. Exit Word by touching the File, Exit menu option. This will return the program control to Vitalink.

8.2.6 Send Data



The satellite dish represents the radio communication function of the Vitalink system. Touch this icon when you want to wirelessly send the data you have collect for a donor case to UNOS. The case does not need to be completely filled in order to send it to UNOS. Each time the case is sent to UNOS, the previous version is overwritten and the latest changes are saved.

The Vitalink communication process notifies the user as to the status of the file which is being sent to UNOS through message boxes. Depending on the size of the file, it may take several minutes for all of the data to be transferred once the satellite icon is touched.

8.2.7 Export



The right arrow represents the export utility. This function initially will not be available during the pilot.

8.2.8 Field History



The binoculars represent the field history function in Vitalink. Every time data is entered into a field, a history is created for that field which can be used later. For example, XYZ Hospital is entered for a donor. Later on, with a new or edited case, the field history icon can be touched to reveal the list of hospitals previously entered. Now the user can touch on the name in the list instead of having to write it out again.

8.2.9 Help



The question mark represents the on-line help utility. On-line help is not available during the pilot.

8.2.10 Exit



The door represent the Vitalink system exit. Touching this icon will close the active case and exit Vitalink.

8.3 Vitalink Forms List

The Vitalink Forms list is based on the AOPO form which is then broken down into logical and manageable sections. The appendix at the end of this document illustrates how the AOPO form was broken up. This list is opened when you create or edit a donor case. Once a case is opened, the list serves as a guide to which sections have been visited. For example, the Case Information form is always the first form which opens when a case is created. In the accompanying diagram, a check

Vitalink Forms	
<input checked="" type="checkbox"/>	Case Information
<input type="checkbox"/>	Donor Information
<input type="checkbox"/>	Consent & Admission Information
<input type="checkbox"/>	Initial Physical Assessment
<input type="checkbox"/>	Assessment Diagram & Comments
<input type="checkbox"/>	Medical/Social History 1-10
<input type="checkbox"/>	Medical/Social History 11-19
<input type="checkbox"/>	USPHS Criteria & Respondent Data
<input type="checkbox"/>	Chemistry
<input type="checkbox"/>	Urinalysis
<input type="checkbox"/>	CBC & Diff
<input type="checkbox"/>	Serology
<input type="checkbox"/>	Microbiology
<input type="checkbox"/>	Hemodynamics/Temperature

mark has been placed next to the Case Information form name. This indicates that Case Information has already been opened. It does not necessarily mean that the section is entirely complete.

8.3.1 Grouping Icons



Since there are a large number of AOPO sections, the grouping icons will display only forms in specific areas.

All Forms



The magnifying class icon represents the function to display all sections of the AOPO form.

Vitalink Forms	
<input checked="" type="checkbox"/>	Case Information
<input type="checkbox"/>	Donor Information
<input type="checkbox"/>	Consent & Admission Information
<input type="checkbox"/>	Initial Physical Assessment
<input type="checkbox"/>	Assessment Diagram & Comments
<input type="checkbox"/>	Medical/Social History 1-10
<input type="checkbox"/>	Medical/Social History 11-19
<input type="checkbox"/>	USPHS Criteria & Respondent Data
<input type="checkbox"/>	Chemistry
<input type="checkbox"/>	Urinalysis
<input type="checkbox"/>	CBC & Diff
<input type="checkbox"/>	Serology
<input type="checkbox"/>	Microbiology
<input type="checkbox"/>	Hemodynamics/Temperature
<input type="checkbox"/>	Intake/Output
<input type="checkbox"/>	Inotropic Support
<input type="checkbox"/>	Cardiac Data
<input type="checkbox"/>	Pulmonary Data
<input type="checkbox"/>	Arterial Blood Gases
<input type="checkbox"/>	Medications
<input type="checkbox"/>	Intraoperative Management
<input type="checkbox"/>	Kidney Data
<input type="checkbox"/>	Left Kidney Anatomy
<input type="checkbox"/>	Right Kidney Anatomy
<input type="checkbox"/>	Heart Data
<input type="checkbox"/>	Lung Data
<input type="checkbox"/>	Pancreas Data
<input type="checkbox"/>	Liver Data
<input type="checkbox"/>	Tissue Data
<input type="checkbox"/>	Notes
<input type="checkbox"/>	Disposition

Patient Medical/Historical Forms



The first aid cross icon represents the function to display only the sections of the AOPO form which have to do with general medical history or administrative forms.

Vitalink Forms	
<input checked="" type="checkbox"/> Case Information	
<input checked="" type="checkbox"/> Donor Information	
<input checked="" type="checkbox"/> Consent & Admission Information	
Initial Physical Assessment	
Assessment Diagram & Comments	
Medical/Social History 1-10	
Medical/Social History 11-19	
USPHS Criteria & Respondent Data	
Notes	
Disposition	

Laboratory Forms



The beaker icon represents the function to display only the sections of the AOPO form which have to do with laboratory results or medications.

Vitalink Forms	
Chemistry	
Urinalysis	
CBC & Diff	
<input checked="" type="checkbox"/> Serology	
Microbiology	
Hemodynamics/Temperature	
Intake/Output	
Inotropic Support	
Arterial Blood Gases	
Medications	

Organ Forms



The heart icon represent the function to display only the sections of the AOPO form which specifically contain organ data.

Vitalink Forms	
<input checked="" type="checkbox"/> Cardiac Data	
Pulmonary Data	
Intraoperative Management	
Kidney Data	
Left Kidney Anatomy	
Right Kidney Anatomy	
Heart Data	
Lung Data	
Pancreas Data	
Liver Data	
Tissue Data	

8.3.2 Launching a Form

To open a form, double tap on the form name in the Vitalink Form list. If you can not see the entire list, use the scroll bar on the right to move the highlight bar up and down.

8.3.3 Closing a Form

To close a form, double tap on the control box in the upper left hand corner of the form or touch the control box once and select Close. All data is saved when forms are closed. Data is also saved when you exit a case because all forms are closed upon exiting.

8.3.4 Minimizing a Form

The user has the option of minimizing forms instead of closing them. This is just another way to manage the data entry process. Minimizing a form gets it out of the way, but does not yet save the information in the form. A minimized form is represented at the bottom of the screen by an icon which matched the Vitalink Form group where it can be found. To minimize a form, touch the down arrow in the upper right hand corner of the form. To restore a minimized form, double tap on the icon at the bottom of the screen or touch the icon once and select Restore.

8.4 Data Entry

The Vitalink system relies on various means to gather donor information. Vitalink can be used on a laptop or on a pen-based computer. This means that the user can set various options to enhance the speed of data entry.

8.4.1 Using the Keyboard

If a coordinator is filling out the donor information at a desk or some other station site, then he or she may want to use the keyboard for quick data entry. The pen in this case is used as the pointing device, like a mouse. Use the pen to select icons, menu items or to open and close forms. Use the keyboard to type in the donor information. The Tab key is used to go from field to field. Using the Alt key in conjunction with the underlined letter in the main menu will gain access to all of the menu options.

8.4.2 Using the Pen

Vitalink is designed to be used anywhere, anytime. All data in the Vitalink system can be entered using the pen alone. However there are several options available to facilitate the data entry process using a pen. They are discussed in the following sections.

Writing in Text Boxes

Each text box is represented by a white box on the form. Data can be entered into the text boxes by writing in them directly, or by utilizing one of several editing features described in the following sections.

Popup Edit Boxes

When the Options, Popup Edit Boxes menu choice is selected, edit boxes appear when the pen touches a standard text box. Text is

written directly in the combs. The title bar of the edit box displays the name of the current field. The icons near the top of the box specify how the data is to be interpreted. The following table explains what each icon does for the recognition of the ink entered:

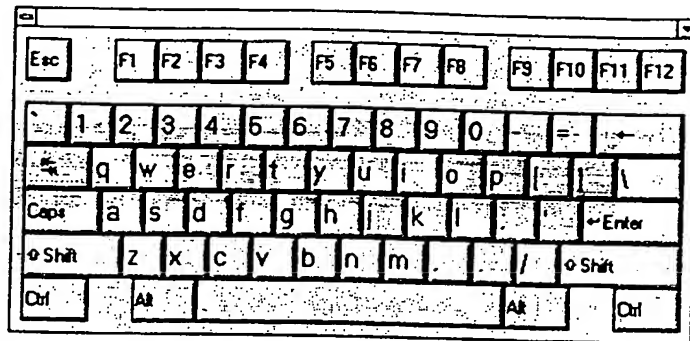
Icon	Interpreted As
	Alpha characters
	Numbers
	Alphanumeric characters

Selecting the appropriate icon for the current field increases the percentage of handwriting recognition. A default icon will be selected depending on the data type of the current field. Touch the OK icon when data entry is complete

The Options Menu controls whether or not the popup edit boxes display. Popup edit boxes can be displayed all of the time, sometimes or not at all. See the Options Menu section for an explanation of the Options Menu choices.

Popup Keyboard

Some users prefer tapping out words with the soft keyboard instead of writing in the field with the pen. This is another tool that coordinators can use to facilitate the entry of donor information.



The Options Menu controls whether or not the popup keyboard displays. See the Options Menu section for an explanation of the Options Menu choices.

8.4.3 Special Editing Tools

In addition to the popup edit boxes and keyboard, there are other editing tools which assist in the data entry process. Each of them are described in the following below.

Check Boxes vs. Option Buttons

A check box is represented as a square box on the form. When a check box is empty, its value is considered false. To mark a check box as true, touch the box with the pen, or tab over to the field and press the space bar on the keyboard. A check box's value can be toggled from true to false and visa versa.

Option buttons are logically grouped together and are mutually exclusive - only one can be marked as true. To select an option, touch the appropriate option button with the pen, or tab over to the field and use the arrow keys to select the desired option. An option button's value is changed by moving or selecting another option button within a group.

Field History

Abington
Philadelphia
Willow Grove

Sample list of Home City entries.

Every time a case is created and data is collected, each data field retains a list of all previous entries. For example "Philadelphia" is entered for the Donor Home City field for a particular case. In subsequent cases, "Philadelphia" will not have to be rewritten, rather the user could touch the binoculars icon and choose a city from the historical list.

Drop-Down Lists

Race
White
Black
Hispanic
Indian Subcontinent
Mideast/Arabian
North American Indian
Pacific Islander

Some fields have specific lists associated with them. The example shown here is the standard UNOS race list. Touch the appropriate choice with the pen to save the data for that field. If you are using a keyboard, tab over to the field and access the drop-down list by pressing the Alt and down arrow keys together. Select the option by using the up and down arrow keys and then press enter.

Date Edit Box

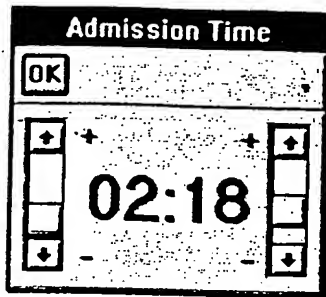
Admission Date						
OK						
◀ February ▶ 1994 ▶						
Su	Mo	Tu	We	Th	Fr	Sa
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28					

Every date field in the Vitalink system displays the date edit box. The user can easily choose the date for the specific field on the calendar. The title bar of the date box displays the current field name. Pick a date by tapping on the appropriate day. Change month and year by pressing the left and right arrows. Touch OK when the correct date has been chosen.

The current date is always the default date. If the date edit is always displaying an

incorrect date, check to make sure your system date and time are correct. See the System Menu section for information on how to change the system date and time.

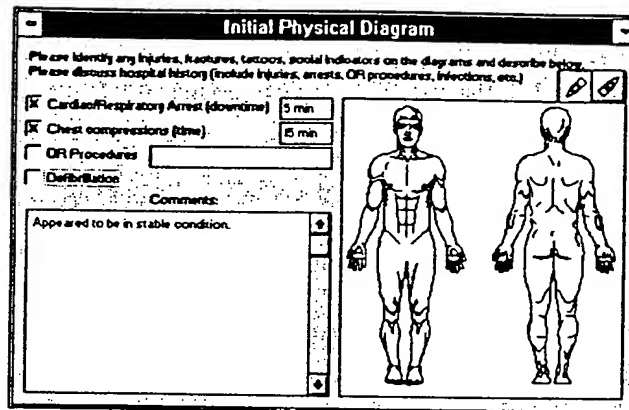
Time Edit Box



Every time field in the Vitalink system displays the time edit box. The user can enter the correct military time by using the up and down arrows on the scroll bars to enter the hour and minute. Touch OK when the correct date has been chosen.

The current time is always the default time. If the time edit box is always displaying an incorrect time, check to make sure your system date and time are correct. See the System Menu section for information on how to change the system date and time.

Using Ink on Diagrams



There are three diagrams in the Vitalink system which can be drawn on:

- ☒ Initial Physical Diagram
- ☒ Left Kidney Anatomy
- ☒ Right Kidney Anatomy

Use the pen just like you would normally. The drawing icons are a pencil facing down (draw mode), and an upside down pencil (erase mode). By selecting one of these icons, ink can be drawn on the diagrams to illustrate scars, tattoos, bruises, etc.

8.5 Data Entry on a Grid

Most of the laboratory data is collected in a grid or table format. Data entry on these forms is basically the same as the standard form with one minor exception. Grid column need to be setup for each snapshot of time. For example, when a new grid form is open, the only data displayed is the name of the rows.

You can not begin to enter date until a new column is created. Once a new column is created, a date and time is established and the following fields are ready for data entry. The following sections explain how this is done.

Date	Time	Test Results
02/24/94	14:01	16:02
Anti-HIV I		
Anti-HIV II		
Anti-HTLV I		
Anti-HTLV II		
RPR-VDRL		
Anti-CMV		
HBsAg		
Anti-HBC		
Anti-HCV		
Other		
Comments		

Column Icons



The plus and minus icons are used to add and delete columns in a grid. To add a new column, touch the plus icon. This will setup a new column with the current date and time. Users can edit the date and time and then enter in data as usual. The vertical and horizontal scroll bars can be used to view more than one column at a time. Users can also resize the grid windows to see more or less rows and columns.

A column must be selected before it can be deleted. To select a column, touch the cell just above the Date field. This will highlight the current column. Touch the minus icon to remove the column and its related data from the database.

9. TECHNICAL SUPPORT

Through the duration of the prototype system, American Management Systems will provide technical assistance from 9 AM - 5 PM EST. Operators will record the necessary information and page a Vitalink system analyst. It is essential when calling the technical support line that you give the operator the following information:

- ☒ Name
- ☒ Phone number
- ☒ Time you can be reached
- ☒ Short description of question/problem

The Vitalink system analyst will return your call as soon as possible.

The phone number for technical support will be given to all users of the Vitalink system during initial training.

Appendix

Vitalink Sections and Corresponding APO Form Page Number

Vitalink Section Name	Corresponding APO Form Page Number
Case Information	1
Donor Information	1
Consent & Admission Information	1
Initial Physical Assessment	2
Assessment Diagram & Comments	2
Medical/Social History 1-10	3
Medical/Social History 11-19	3
USPHS Criteria & Respondent Data	3
Chemistry	4
Urinalysis	4
CBC & Diff	4
Serology	4
Microbiology	4
Hemodynamics/Temperature	5
Intake/Output	5
Intropic Support	5
Cardiac Data	6
Pulmonary Data	6
Arterial Blood Gases	6
Medications	7
Intraoperative Management	7
Kidney Data	8
Left Kidney Anatomy	8
Right Kidney Anatomy	8
Heart Data	9
Lung Data	9
Pancreas Data	9
Liver Data	9
Tissue Data	9
Notes	10
Disposition	11

UNOS **Organ Information** **Service**

Design Document

September 23, 1994

UNOS United Network
for Organ Sharing

ams

American Management Systems, Inc.

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EXECUTIVE SUMMARY

American Management Systems, Inc. (AMS) is pleased to present the United Network for Organ Sharing (UNOS) with the Design Document for the Organ Information Service (OIS). The OIS will revolutionize the transplant process by providing Organ Procurement Coordinators with a new way to collect and communicate donor data.

The OIS is a data collection and dissemination tool designed for the unique requirements of the organ sharing community. It is application software combined with various types of mobile computers and communication methods. OIS will compress the existing transplantation process by capturing donor information in an electronic format in the field and by supplying a network for donor information communication.

The OIS will be used by Organ Procurement Coordinators in the field to collect donor information and to transmit the data to UNOS headquarters. The coordinator will have an interface to the UNOS Match Run through the OIS. The communication of donor information to members of the transplant community may be done electronically through the OIS system, or sent through the OIS fax and pager gateways. Donor information will also be accessible through a touch-tone phone.

The data elements collected by the OIS are combined from three main sources: the Association of Organ Procurement Organizations form; the UNOS Cadaver Donor Registration form; and the Match Run donor record. The data collected in OIS can be considered UNOS's donor data collection form.

The OIS Design Document is meant to serve as a guide during the development phase for the AMS and UNOS project teams. As development progresses, the design may need to change to accommodate various circumstances. Any changes to the design will be documented and presented to UNOS for approval. The complete OIS will be delivered to UNOS in January, 1995.

BACKGROUND

Originally established in 1977 by members of the South-Eastern Organ Procurement Foundation (SEOPF), the United Network for Organ Sharing (UNOS) operates the national Organ Procurement and Transplantation Network (OPTN) and the national Scientific Registry for Organ Transplantation. In this role, UNOS functions as a contractor for the federal government and a private, non-profit corporation. Under contract with Health Resources and Services Administration (HRSA), UNOS has operated the OPTN since September 30, 1986, and the Scientific Registry since September 30, 1987.

American Management Systems, Inc. (AMS) is the developer of the Organ Information Service (OIS) application software in conjunction with UNOS. AMS is based in Fairfax, Virginia. Founded in 1970, AMS specializes in helping clients improve their performance through the intelligent use of information technology. AMS combines specific industry experience, business function expertise, proven systems development practices, and an extraordinary depth of technological competence to help our clients meet their business goals.

The following statements were taken from the 1993 UNOS Annual Report and describe the Health Resources and Services Administration (HRSA) goals for the National Organ Procurement and Transplantation Network (OPTN):

- Improve the effectiveness of cadaver organ procurement and distribution.
- Increase patient access to state-of-the-art transplantation technology.
- Improve the system for sharing renal and extra-renal organs so as to
 - facilitate matching of donors and recipients, based on specific criteria established for each organ,
 - improve transplantation outcomes,
 - provide a system by which immunologically sensitized patients are afforded the best possible opportunity to be matched with a compatible donor, and
 - decrease the wastage of organs.
- Assure quality control by collection, analysis, and publication of data on organ donation, procurement and transplantation.
- Maintain and improve professional skills of those involved in organ procurement and transplantation.

The OIS will provide the foundation for improvements in each of the above areas.

In November, 1993 UNOS and AMS met to discuss how to change the current donor information gathering process from a serial/manual method to an efficient parallel/automated process. The number one goal of implementing an automated donor information process is to save more lives. UNOS wants to provide a mechanism to collect the required donor information in the field and have that data transmitted electronically back to UNOS headquarters. Automating this initial process encompasses the scope of the original Vitalink prototype.

The Vitalink prototype automated the collection of the data on the Association of Organ Procurement Organization's (AOPO) form. The prototype, complete with wireless data communications, was delivered on January 31, 1994. The Pilot Results Report was delivered on April 29, 1994.

The Vitalink prototype as it exists today is a data collection tool designed for the unique requirements of the organ sharing community. The prototype consists of custom application software combined with pen-based, hand-held computers and wireless data communications. Vitalink supports Organ Procurement Coordinators in the field by collecting and transmitting the essential donor information to the UNOS Organ Center so that a Match Run can be executed at UNOS. Vitalink provides a mechanism to standardize the data collected on donors to increase the chance of organ placement.

Through the feedback gathered from the pilot, AMS has concluded that the most important issue is to not only to collect the data, but to make the data available to all of the professionals involved in the transplantation process. UNOS will expand its role in the organ transplant community by becoming the national clearinghouse of organ sharing information. The OIS system achieves this objective by utilizing the Lotus Notes platform.

Lotus Notes provides the infrastructure on which UNOS can build its long term vision of an automated organ information sharing system.

July, 1994 marked the start of the design phase for the production system referred to in this document as the Organ Information Service (OIS). The OIS encompasses the collection of data from three sources: The AOPO form, the Cadaver Donor Registration (CDR) form and the Match Run donor record used to run matches at UNOS. OIS facilitates the access to essential donor information to all appropriate transplantation professionals.

During the months of July and August 1994, AMS and UNOS conducted further requirements analysis for the OIS system.

Meeting Date	Location	Purpose
July 7	UNOS	Design kick-off
July 12 - 13	UNOS	Data fields and Match Run review
July 28	UNOS	Requirements analysis
August 2	UNOS	Requirements analysis
August 22	AMS	Match Run planning
August 24	UNOS	Lotus executives briefing
August 26	UNOS	Match Run staff questions and review
September 1	AMS	Organ Center staff members input
September 16	AMS	Review of design document

The design of OIS has been an ongoing process since the start of this project in November, 1993 and has resulted in the culmination of this document.

INFORMATION STRATEGY

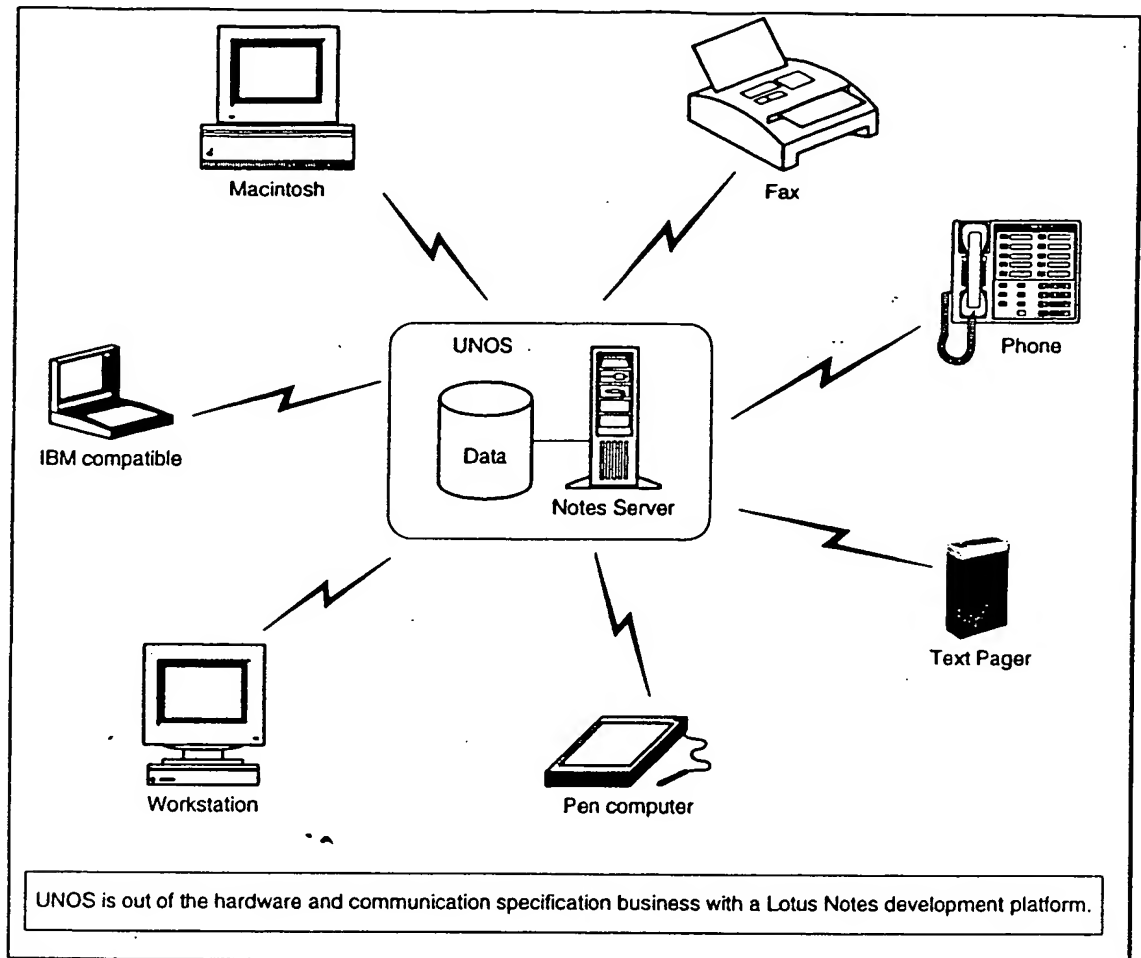
In order to be useful, information should be stored in a way that makes it readily accessible to those who need it most. Lotus Notes is a platform in a new class of systems called "groupware". These systems have emerged because traditional tools were not designed to support the creation, flow, and tracking of information in direct support of business processes. Lotus Notes has an architecture designed specifically to support the management and sharing of knowledge while traditional database systems are transaction-oriented and cannot easily support occasionally connected users.

An organizations' knowledge system should be:

- Extremely open
- Topology-independent
- Designed to support the sending and sharing models

When putting together an information strategy, it is important to understand the difference between back-end information storage systems and front-end tools that act upon the information itself. A back-end information storage system can be thought of as the infrastructure that stores and disseminates information throughout the organization. It is the middleware that works in conjunction with operating systems and networking software in order to manage the distribution of data and to ensure the security of the system.

Dictating which hardware and communication methods to use is risky. Technology changes daily and many organizations and users have strong emotional feelings about the purchase of hardware. Lotus Notes runs on the most widely used operating systems and hardware including IBM compatible workstations, notebooks, sub-notebooks, pen-based computers, and Macintosh products. By developing on the Lotus Notes platform, users are not limited to specific operating system, hardware and communication options.



The feedback gathered from the Vitalink prototype dictated that UNOS must think beyond the concept of providing a data collection tool (Vitalink) and concentrate on setting strategies that involve back-end infrastructure deployment (OIS). Lotus Notes provides a platform that meets the needs of the OIS and provides a foundation that may be used to manage all information aspects of the organ placement process.

THE NOTES PLATFORM

This section is a compilation of information taken from "Lotus Notes: A System for Managing Organizational Knowledge" published by Lotus Notes Support Services.

Notes is a platform that is specifically designed for the development of customized, communication-based or information-based applications. Lotus Notes was first deployed in 1989. Today there are over 500,000 site licenses of Notes.

Client/Server Architecture

Notes is implemented as a modular, client/server system with support for many operating environments both on the client and server sides. Access to the data is controlled by the server at a very fine level of granularity, which requires a smaller amount of data to be passed between a user's workstation and the remote server. Clients are available on Windows, IBM OS/2 Version 1.x and 2.x, Macintosh System 6 and 7, and various UNIX implementations. Servers are available on all the above with the exception of the Macintosh, and is available as a Netware Loadable Module (NLM) for Novell's Netware network operating system.

Open Standards

Notes supports a wide range of industry standards that provide the ability to move data into and out of Notes using standard formats and protocols in addition to the Notes API:

Messaging standards, X.400 and the Vendor Independent Messaging group (VIM);

Naming standards, X.500-compliant hierarchical naming;

Authentication, X.509 Notes is an industry leader in the use of public key/private key cryptography in the areas of authentication and messaging;

Encryption, Notes licenses the RSA Public Key Cryptosystem developed at MIT and licensed by Public Key Partners/RSA, Inc. and utilizes this set of services in all aspects of Notes security;

Bento, Lotus plans to embrace the cross platform document architecture in future releases;

SQL, Notes will support connectivity to relational databases through ODBC (the Windows Open Database Connectivity interface);

Openness at all levels, Notes is designed so that each of its base services may be augmented or replaced by components provided by a third-party vendor.

Replication

Notes uses a process called replication, which is the process of keeping multiple copies of a database in synchronization with each other. The replication process is optimized for broad dissemination of information shared among many individuals. Replication supports virtually any topology and is the centerpiece of the occasionally-connected usage model.

Scaleable Implementation

The Notes server was designed with scalability in mind. As more clients are added to the system, the Notes server may be upgraded to a more powerful hardware platform. Notes has just released its NLM server and has plans for a Windows NT version.

Distributed Manageability

In a system consisting of potentially many servers, it would not be feasible to have a network administrator assigned to every server. Notes allows any server to be managed and configured remotely. Notes servers generate alerts that can be fed to network administrators through electronic mail. UNOS will need to invest time into training one or more of their IS staff to become Lotus Notes administrators.

System Updates

Notes not only replicates data, it also replicates changes made to Notes applications. Design changes are replicated throughout the user community automatically when users connect to the server at UNOS.

Security

Lotus Notes was developed from the outset as a secure system. Done in a manner that works *across vendors' operating environments*, Notes utilizes technology licensed from RSA, Data Security, Inc., the industry leader in cryptographic algorithms and services. Notes provides four classes of security:

Authentication, which securely identifies users using the industry-standard X.500 hierarchical naming syntax. Authentication in Notes is bi-directional, that is, servers authenticate the identity of users *and* users authenticate the identity of servers. Authentication is used whenever a user and a server, or two servers, are communicating with each other.

Digital Signatures, which provide users the absolute guarantee that a given message is from who it says it's from, essentially a *user-to-user* form of authentication. In addition, this technology enables the computer to *notarize* all or a portion of a message, thus making the guarantee to its recipient that the message has neither been forged nor altered in transit.

Access Control, which provides the ability to grant or deny access to shared databases, documents, views, forms, and fields. Server access can also be controlled for individual users by either allowing or denying access to specific Notes servers within the organization.

Encryption, which involves ciphering or scrambling information so that even if it were accessed by the wrong individuals, it couldn't be understood. Encryption is available at three levels in the system. At the *message* level, individual messages can be encrypted for one or more intended recipients; At the *network* level, encryption prevents someone from promiscuously "sniffing" (tapping into) traffic on a LAN or dial-in line, because they won't see anything intelligible; at the field level, databases can be designed to encrypt document fields so that only specified users can read them.

The security in Notes works across vendor platforms, so it is managed and dealt with in the same way regardless of which operating system you choose to use. It works with any topology that you choose, so that occasionally-connected users or LANs are managed the same way as a single server or LAN.

Lastly, *there are no back-doors into the system*. Because of its fundamental design, neither Lotus nor any hacker, foreign or domestic government agency, or competitor has or will have a "super user" capability in a Notes information system.

Open Data Integration

In addition to inter-application data exchange facilities, a second level of data integration is achieved through use of Notes' set of import/export filters. Local organ procurement organizations may use import/export filters to exchange data with their own Donor Management Systems (DMS).

Dial-Up Notes

Dial-up Notes allows the use of Notes at remote sites where there is no LAN-based Notes installation. Notes will work with most popular brands of symmetrically modulated modems which recognize the Standard AT Command Set (the commands used in Hayes Smartmodems up to 2400 bps). Notes supplies modem command files for over 60 models, in addition to a template and instructions for creating new files for uncertified modems. Dial-up Notes supports asynchronous communications scripts to allow connections to X.25 networks and other applications that require extended communications support.

Notes Mail

Lotus Notes contains a world-class mail and messaging system that has an interface designed to be easy to use and consistent with that of the rest of the Notes product.

NOTES DEVELOPMENT TOOLS

After Notes had been chosen as the infrastructure on which to base OIS, AMS evaluated development tools that offer an alternative to the standard Lotus Notes interface. Three alternative development tools were evaluated:

Lotus Forms

Lotus Development Corporation announced the availability of Lotus Forms on June 27, 1994. Lotus describes Lotus Forms as "a powerful, production form workflow solution based on a messaging-reliant, client-based workflow model with sophisticated routing, tracking and security." Lotus Forms offers a development environment for form-based workflow systems.

Visual Basic

Microsoft Visual Basic was used for the Vitalink prototype and was considered as an alternative interface to the Notes infrastructure because of its support of Pen aware objects. VB is a programming language for Microsoft Windows that includes a robust development environment as well as extensive third party support for extended objects. Visual Basic has been the GUI language of choice for the AMS Mobile Computing Group for the past two years. VB/Link for Lotus Notes is a VBX for Visual Basic that enables VB to read and write Notes data.

Lotus ViP

Lotus Development Corporation announced the availability of Lotus ViP Visual Programmer for Notes on June 28, 1994. ViP is "a visual application development environment that combines the power of Lotus Notes with unique Visual Linking tools to enable corporate developers, Lotus Business Partners and ISVs to build a new class of strategic groupware applications. Notes ViP extends the market-leading Notes groupware platform in four key areas: integration of Notes and corporate data stores; building of sophisticated graphical user interfaces; enhanced programmability in the Notes development environment; and the ability to create complex reports, charts and graphs." The ViP language is based on LotusScript 2.0, a BASIC-compatible language that has been enhanced to allow development of event-driven applications.

Conclusion

Lotus Forms would not be effective for the OIS because it supports a different data model than that required by the OIS.

Both VB and ViP are excellent GUI development environments, but do not provide tight enough integration with Notes to provide a seamless application. VB and ViP should be used when data needs to be integrated from many sources, and when it is necessary to chart and report Notes data. Notes itself was designed to manage data entry and retrieval of form based data. If the OIS application was developed in VB or ViP, the user would be required to perform

some actions from the Notes client software. It is necessary for the user to understand Lotus Notes client software. If the OIS application is written outside of Notes, the user must learn that interface as well. Having the user jump from the VB/ViP OIS system to the Notes client software would make the system appear fragmented and confusing. The OIS application needs to be in one environment that can provide consistency of interface, and tight integration of all components.

Notes databases are more than just databases, they are applications that contain views, forms, and system logic. Notes servers must retrieve data for clients based on views and forms that must be developed and stored in each Notes database. The Notes application must be developed before a VB or ViP application is designed. If the OIS were developed in VB or ViP it would emulate the forms and views that already exist in the Notes database. A Notes application interface developed in VB or ViP is only a shell and extension to an existing Notes database application.

The OIS is based on the ease of remote user communications. VB does not support dialing in to a Notes server and ViP only supports a very limited dial up capability. For example, ViP requires the user to go into the actual Notes client software to hang up a remote connection.

Graphics can only be stored in a Notes Rich Text field which VB and ViP do not support. The OIS application needs to have diagrams that the user may annotate.

VB and ViP offer excellent GUI design environments and contain a better scripting language than Notes. This makes it tempting to use VB or ViP to develop OIS, but because VB and ViP lack a tight integration with all of the Notes components, AMS believes it would be risky to develop OIS using VB or ViP. Lotus Notes 3.11 offers an integrated environment that contains all of the components necessary to build an effective system to collect, manage, and communicate donor information.

SYSTEM OVERVIEW

This section contains a general description of the Notes concepts that make up the OIS application.

Notes Databases

In Lotus Notes, the database is the foundation of the application; it is possible to use the terms "application" and "database" interchangeably. A Notes database is a collection of related documents stored in a single file. In Notes, each database is represented on the workspace with an icon. Information in a database is organized and maintained with five basic building blocks: forms, fields, sections, views, and documents.

Documents

Lotus Notes uses a document oriented database. Documents are the "records" in the OIS application; it is similar to a "row" in a relational database. Information in a document may be entered by a user, calculated by formulas incorporated in the database design, imported from other applications, or linked to another application and dynamically updated. Like the database itself, a document can be any size. A single document may contain only a few alphanumeric characters, or several pages of text and graphics.

Forms

A form defines the format and layout for documents. Each form can contain fields, static text, graphics, and buttons, which determine how users enter information, and then how that information is processed and displayed. When you compose a document, the form that you are using determines which fields are included in your document, and how they are placed. If you later view that document through a different form, you may not see all of the same fields.

A database can have any number of different forms, according to how it is used. For example, the OIS Donor Information database contains Donor Information forms, ROP Tray Data forms, and Match Run forms.

Fields

A field is a named area of a form that contains a single type of information. A form can have an unlimited number of fields. Depending on its data type, the value of a given field can be as small as a single character, or many pages of text and graphics.

Sections

A section is a special type of field that logically defines an area of a form or document. Within a section, you place fields and static text; access to that

section of the document can then be controlled so that only authorized users can edit the data within the section.

Views

A view is a tabular summary of the documents in the database. Most databases have several views, each sorting, selecting, and categorizing the documents in a different way. For example, the Donor Information database may order documents by donor name in one view and by UNOS ID in another. Each row in a view represents a document. Views are used by users to access documents in a database.

Security

The OIS system utilizes all aspects of Notes security but there are two levels of security that an OIS user should understand; database level and document level. Users of the OIS system are given a default type of access to a database and are given the ability to refine access control at the document level to allow access to those who *need* to see donor information.

The access control list (ACL) of a Notes database consists of:

- No Access - Absolutely no access to the database; users can not even add the database icon to their workspace.
- Depositor - Users can compose documents, but can not read any - not even the ones they composed.
- Reader - Users can read documents, but can not compose any.
- Author - Users can compose documents, read documents, and edit the ones they composed.
- Editor - Users can compose documents, read documents, and edit any document regardless of who composed them.
- Designer - Users have Editor access, plus they can modify the database icon, About database document, Using database document, and all design elements (fields, forms, views, and macros).
- Manager - Users have designer access, plus they can define replication settings, modify the ACL, and delete the database.

In addition to the access levels described above, Notes provides options that control whether a user can create or delete documents.

The OIS system will also utilize two special fields in some documents called Author Names and Reader Names.

Author Names is a text list of user names that indicates who can edit a given document. The author names field cannot override the access control list, it can only refine it. Users who have been assigned an access level of No Access to a database can never edit a document, even if they are listed in the document's Author Names field. Any user with Author access to the database who is listed in the Author Names field has read and write access to the document, even if he or she did not create the document.

The Donor Information document will contain a Author Names field that is editable. This field will always contain the user name of the person saving the document. The author may add names of other users to the Author Names field allowing them to edit the document as well. One person should manage the editing of a document to prevent editing conflicts, however the Author Names field may be used if the case is being passed from one coordinator to another.

Reader Names is a text list of names that indicates who can read a given document. Reader Names is similar to Author Names, except that it controls read access to a document instead of edit access. This is a very important field in the OIS system because it controls not only who can read a document, but who can replicate the document to their local machine. Users whose name does not appear in the Reader Names field will not even know that document exists.

Replication

Replication is the process of synchronizing two Notes databases. Users in the field will dial in to the OIS Notes server and replicate their copies of OIS Notes databases with the OIS Notes databases on the server. It is important to understand that all data and relationships between the data are stored locally *and* on the Notes server. When a user modifies a Donor document on their local machine that modification cannot be seen by others until replication occurs.

When users replicate the Donor Information database, only documents that have that user in the Reader Names or Author Names fields get replicated between the user and the server. The field user will not receive all of the Donor Information documents that are on the server, they will only receive the ones they have composed, and the ones that have their user name in the Reader Names field.

All data validation and system databases are also replicated with users in the field to ensure that local copies of reference databases are up to date and accurate.

OIS In The Field

This section will briefly describe the way a Organ Procurement Coordinator might use the OIS to manage donor information during the placement process.

1. After consent has been obtained and the coordinator begins to gather donor information, the coordinator selects the Donor Information database on their Lotus Notes desktop and composes a new Donor Information document.
2. After the coordinator has entered enough information in the document for a Match Run, they press the Request Match Run button on the Donor Information Match Run Input form. The OIS will check the Match Run Input data and issue warnings for data that is invalid. Some errors will require correction, such as missing data in a required field, but most error messages give the user the ability to proceed with the Match Run. Following data validation, the OIS field unit calls the OIS Notes server in Richmond and delivers the Donor document to the Match Run Request database.
3. The coordinator may disconnect from the Notes server after the Donor document has been transmitted, or may remain connected to wait for the

Match Run Results. The user will receive a mail message from the Match Run process indicating success. The coordinator may then replicate the new Match Run Results document to their field unit and view it.

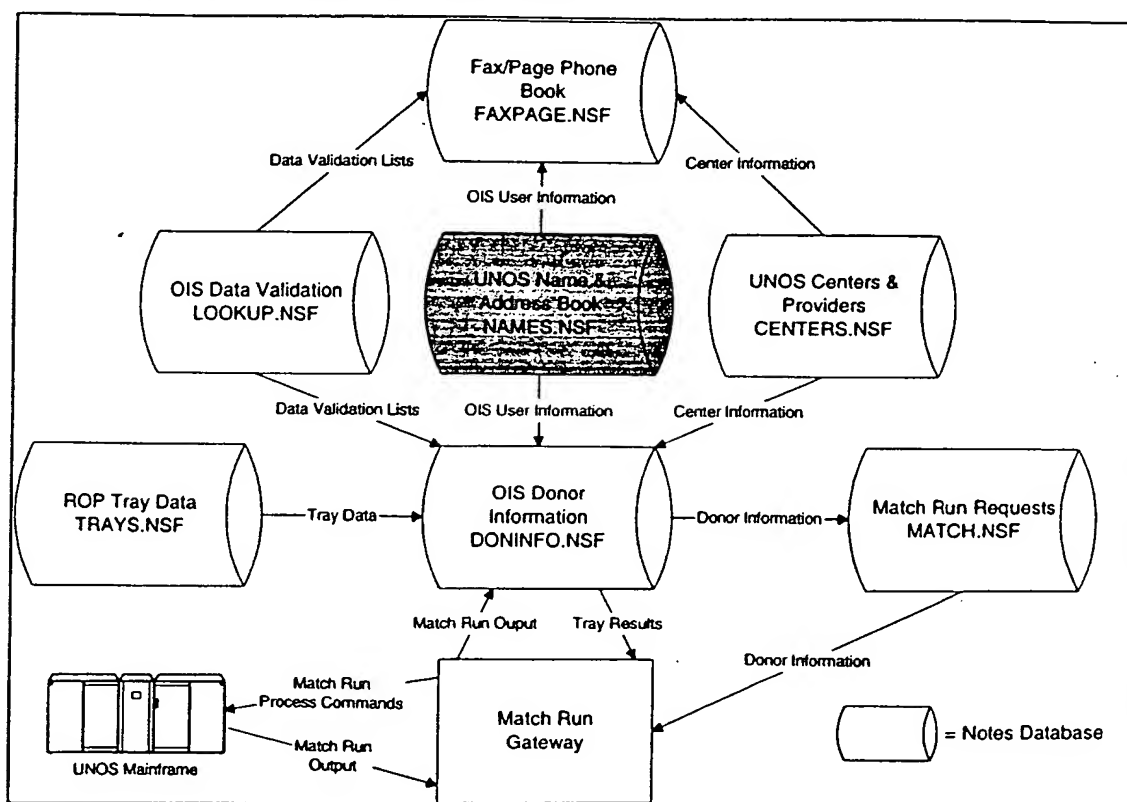
4. After the coordinator reviews the Match Run Results, the coordinator may wish to send fax or page notification to a person or center. To send a page notification, the user presses the page button on the Match Run Results form to compose a Pager form. The Pager form can be addressed to a center or an individual that has registered their pager with the OIS to notify them when donor information is available.
5. Once the Notification documents have been created, the coordinator needs to replicate with UNOS to forward the Notification documents to the fax and/or pager gateways.
6. If a center receives a page or fax notification and they have a Notes client, they may replicate with the OIS server to receive the donor information. The center may also call the Phone Notes client with a standard touch-tone phone to request a fax of the donor information.

OIS NOTES DATABASES

The OIS involves the creation of a Lotus Notes network for UNOS. The network topology for this network is fairly simple because it consists of one Notes server, UNOS_OIS_1, that is accessed by remote users via modem or by the UNOS Organ Center over the UNOS Pathworks network. This section describes each of the Notes databases that comprise the OIS application.

The User Access sections in this document explain the OIS field user's access level of each database. OIS system administrators have Manager access to all OIS Notes databases.

UNOS's Public Name & Address Book



Description

The UNOS Public Name & Address Book contains a directory of the OIS users as well as a set of documents for server communications and management. When a user is registered in the OIS, a person document is created for that user in the Name & Address book. The person document contains e-mail addressing information, contact numbers, personal and miscellaneous information. When registering users with the OIS, the system will take advantage of Lotus Notes distinguished naming to supply user names. A Notes user name can consist of

the user's name, 0-4 organizational units, organization, and country. The OIS will use center names for the organizational units. The user name of a coordinator from the Indiana Organ Procurement Organization might be:

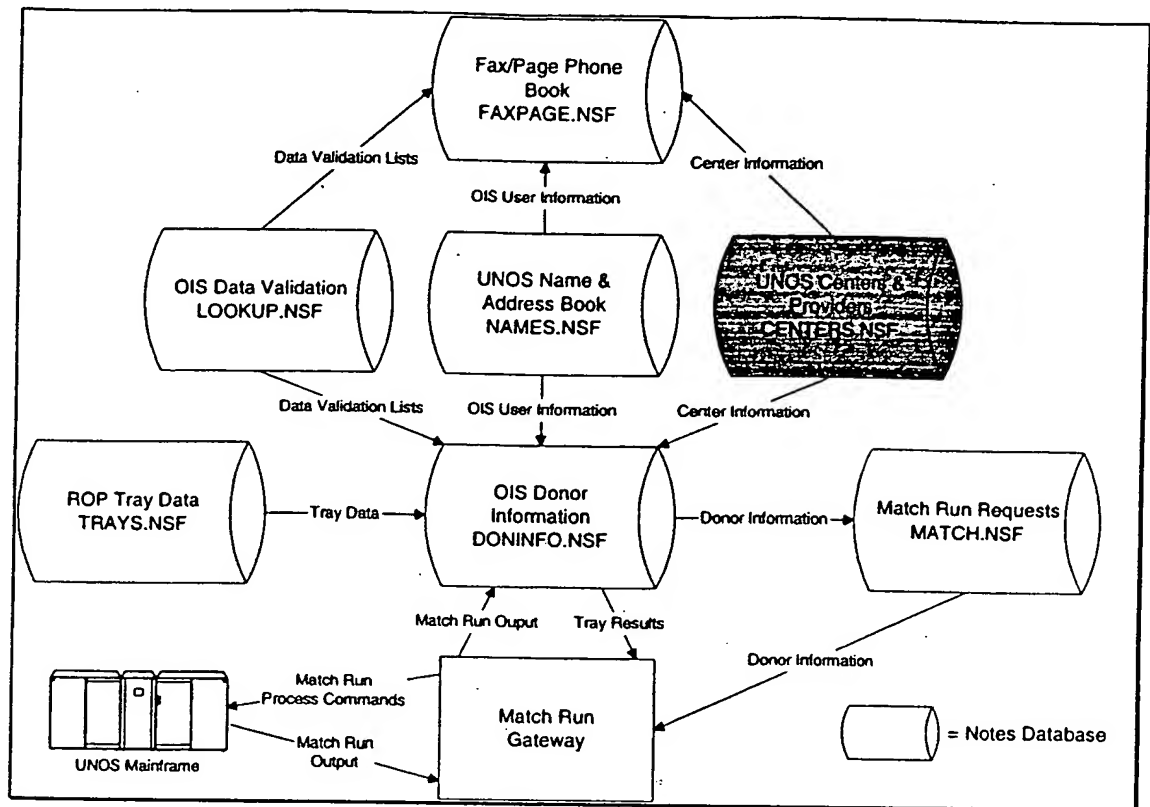
"Joe Smith/INOP/UNOS"

Because the OIS is based around the concept of data sharing, it is important to be able to uniquely and easily identify other users of the system. Users who author donor information in the system have the ability to grant Reader access to other users of the system. The Name & Address book contains the names of all the OIS users as well as groups that contain multiple users. The Name & Address Book will have a group name for every center that contains all of the OIS users in that center. This allows a coordinator to grant Reader access to individual users by using user names, or to all users at a particular center by using group names. The Name & Address book is critical to the movement and sharing of data in the OIS system.

User Access

All field users will have Reader access to this database.

UNOS Centers & Providers



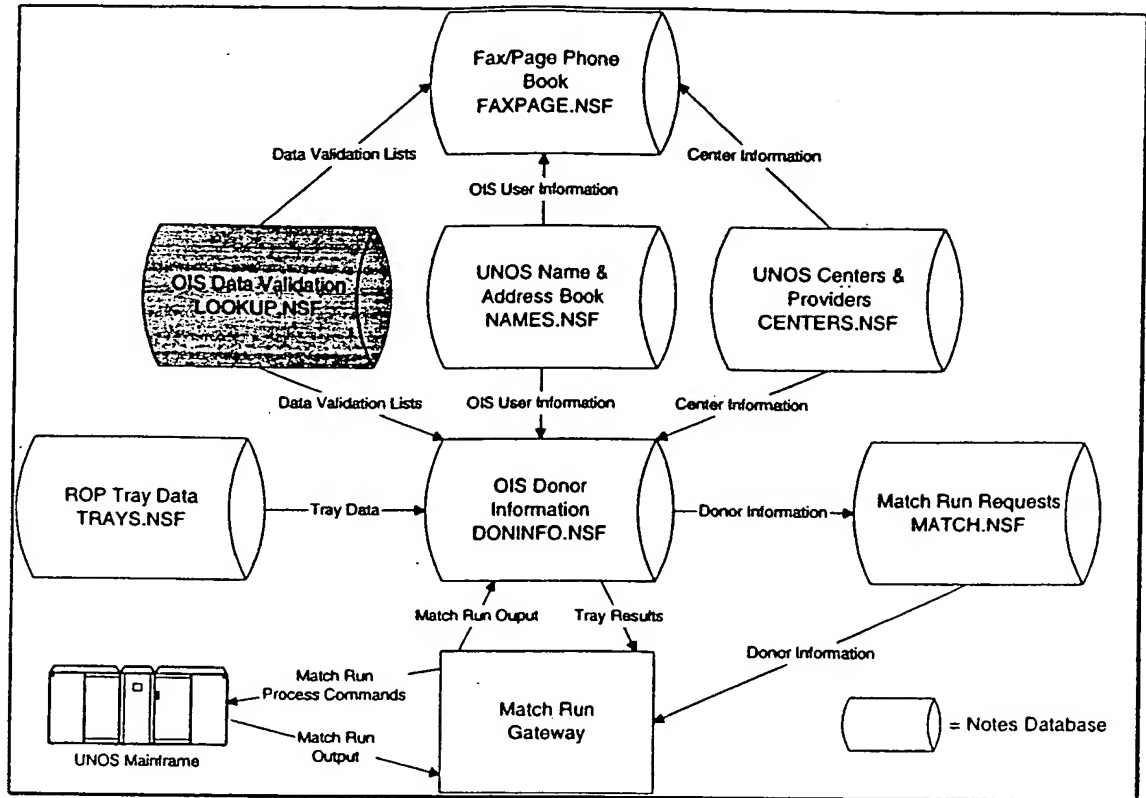
Description

The UNOS Centers & Providers database contains a document for every center and provider that is registered with UNOS. Center documents contain information used by the OIS system as well as page and fax contact numbers. The center name in a user's distinguished name must be one of the center names in this database. This database will be used for data validation when entering center and provider information in the OIS Donor Information database, and will be used to associate Match Run variances with centers.

User Access

All field users will have Reader access to this database, with the ability to modify the center document of the center to which they belong. This database may be viewed by users for reference but it is primarily designed for system access.

OIS Data Validation



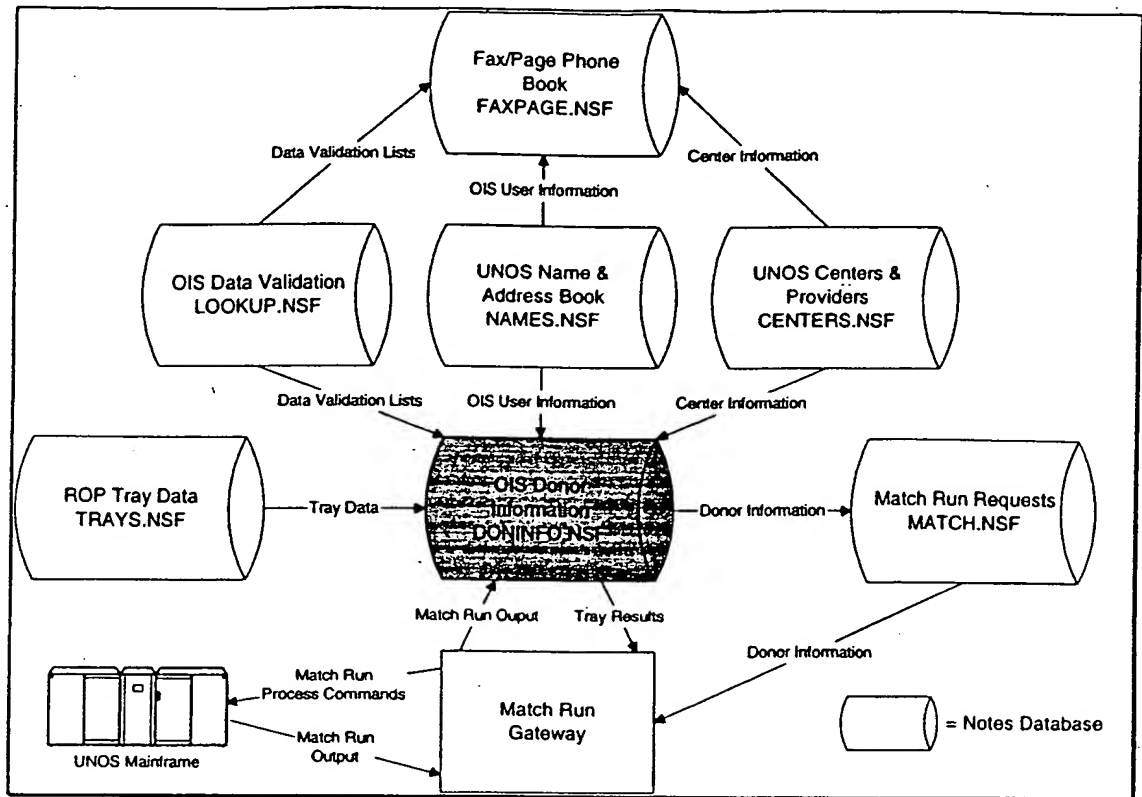
Description

This database contains all of the field level lookup data used in the OIS application for lookups and data validation. Reference data may be updated by the OIS system administrator. Any OPO that may have their own Donor Management System will be able to export this database to ASCII files to have the most current data validation lists.

User Access

All field users will have Reader access to the OIS Data Validation database. This database may be viewed by users for reference but it is primarily designed for system access.

OIS Donor Information



Description

The Donor Information database is the heart of the OIS system. This is where the coordinators enter all donor information and other OIS users come to view or print donor information. The following sections outline what is contained in the Donor Information database and how it interacts with other databases in the OIS application.

The Donor Information database consists of three major documents:

- Donor Information
- Match Run Results
- Tray Results

This database is unusual in the fact that there are over 25 different forms used to view the Donor document. In the other OIS Notes databases, each *document* (a record in the database) has only one *form* (record layout) to view that document with. Each form will read and write data to the same Donor document, but will provide access to different sections of the Donor document. A field from the Donor document may appear on more than one form, but points to the same data in the document. This concept allows the OIS to logically group sections of data and present subsets of the Donor document to the user.

User Access

The documents in the OIS Donor Information database have two special fields called Reader Names and Author Names. When a document is composed, that user's name is placed into the Author Names field. All users are granted Author access to the database as a default. This means any user can compose and save a new document, and then edit that document at a later time, but the user is not allowed to edit a document they did not author. Notes keeps track of who can edit a document via the Author Names field. If the author of a document adds other user names to the Author Names field, then those users may edit the document even though they were not the original authors.

The Reader Names field allows the author of a document to limit who can view the document. Only users whose name appears in the Reader Names or Author Names field can view a document. The Reader Names field will always contain a group of system administrators, the UNOS Organ Center, and the current user. The author of the document may add user names to the Reader Names field to grant them access to view the document. Users listed in the Reader Names field may not edit the document. Only users listed in the Author Names field may edit the document. This enables the coordinator to control who may view and edit their case.

The users in the Organ Center have Editor access to the OIS Donor Information database. They will be able to view all documents in the database because a group containing the names of the Organ Center users is always contained in the Reader Names field of each document. The Organ Center will also be able to modify any document in the database even if they are not in the Author Names field because they will be granted Editor access to the database through the access control list by default (all other users will be given Author access).

Donor Document

The most data-intensive OIS document is the Donor document. The Donor document has over 25 forms used to enter data. All of the fields contained in the forms are located in the Appendix. Each form is described in the following paragraphs.

Donor Document Forms

- Donor Form Navigation
- Case Information
- Donor Information
- Consent & Admission
- Initial Physical Assessment
- Medical/Social History
- Chemistry
- Urinalysis
- CBC & Diff
- Serology
- Microbiology
- Hemodynamics/Temperature
- Intake/Output
- Arterial Blood Gases
- Medications
- Cardiac Data
- Pulmonary Data
- Intraoperative Management
- Kidney Data
- Heart Data
- Lung Data
- Pancreas Data
- Liver Data
- Tissue Data
- General Notes
- Organ Recovery
- Match Run Input

The Donor document was created by using the data collected from three sources:

- Association of Organ Procurement Organizations form (AOPO)
- Cadaver Donor Registration form (CDR)
- Match Run Donor record (MR)

Some of the data fields overlap, and some were unique to each source. This new Donor document will be UNOS's standard form for collecting donor information used to place organs.

Every Donor document form will have navigation buttons at the top, allowing users to quickly and efficiently move from one part of the form to another.



The Previous and Next buttons move the users from form to form in the order listed above. The Jump button pops up a list of Donor document forms the user can choose to move to. The Print button displays a list of Donor document forms the user can choose to print. The user may choose one or many sections to print, or select the 'All Forms' option in the list to print the entire Donor document. The Home button returns the user to the Navigation form which is described in the next section.

Donor Form Navigation

Home Jump Print Prev Next

DIS ID: 092094130712345 UNOS ID: HIT847 Donor Name: Bryan Lilley

Go To Form

- ☒ Donor Form Navigation
- ☐ Case Information
- ☐ Donor Information
- ☐ Consent & Admission
- ☐ Initial Physical Assessment
- ☐ Medical/Social History
- ☐ Chemistry
- ☐ Urinalysis
- ☐ CBC & Diff
- ☐ Serology
- ☐ Microbiology
- ☐ Hemodynamics/Temperature
- ☐ Intake/Output
- ☐ Arterial Blood Gases
- ☐ Medications
- ☐ Cardiac Data
- ☐ Pulmonary Data
- ☐ Intraoperative Management
- ☐ Kidney Data
- ☐ Heart Data
- ☐ Lung Data
- ☐ Pancreas Data
- ☐ Liver Data
- ☐ Tissue Data
- ☐ General Notes
- ☐ Organ Recovery
- ☐ Match Run Input

The Navigation form is another utility used to guide the user through the forms of the Donor document. Pressing the Home button will return the user to this form. Each section of the Donor document is represented in a list. Users may move to different forms by selecting a form name in the list and pressing the Go To Form button.

The Navigation form is also where coordinators will have the ability to grant Reader access to other users for their case as well as send fax and pager notification to coordinators and centers.

Only the most basic fields are on the Navigation form. This includes fields such as the OIS identification number, donor name and UNOS ID.

Case Information

The Case Information form contains general information about the donor case. Fields include the coordinator's name and phone number, OPO name, donor hospital information and admission date and time.

Lookup Fields

Field Name	List Name
CaseType	CaseType
ReferralType	ReferralType
DonorCenterName	Centers file
DonorCenterCode	Centers file

Donor Information

The Donor Information form houses all of the demographic data, initial blood and HLA typing of the donor. This is also where the user indicates the cause of death and whether or not the case is under review by the Medical Examiner.

Lookup Fields

Field Name	List Name
CauseofDeath	CauseofDeath
MechanismofDeath	MechanismofDeath
CircumstancesofDeath	CircumstancesofDeath
Race	Race
A1 and A2	AHLA
B1 and B2	BHLA
DR1 and DR2	DRHLA
ABO	ABO

Consent & Admission

The Consent & Admission form has organ consent information in the same format as the CDR form. Users indicate if consent was requested and/or obtained by checking yes or no for each organ. If request or obtained answers are no, then the user enters in the appropriate reason code. The admission section is where users record information about how and why the donor was admitted to the hospital.

Lookup Fields

Field Name	List Name
ApproachedBy	ApproachedBy
KidneyObtainedReason	OrganConsentReason
LiverObtainedReason	OrganConsentReason
IntestineObtainedReason	OrganConsentReason
PancreasObtainedReason	OrganConsentReason
HeartObtainedReason	OrganConsentReason
LungObtainedReason	OrganConsentReason
TissueObtainedReason	OrganConsentReason

Initial Physical Assessment

The Initial Physical Assessment form mimics page 3 of the AOPO form. Pulmonary, Cardiovascular, Gastrointestinal, Genitourinary and Musculoskeletal areas are assessed and recorded in this form. The form also contains a picture of the human anatomy that the coordinator may annotate with text and graphics.

Medical/Social History

The Medical/Social History form is one of the larger forms in the Donor document. This form is divided into three sections. The first section gathers data about who is responding to the questions and what their relationship is to the donor. The second section contains questions that are specific to UNOS. These questions are taken directly from the CDR form. The last section is the entire USPHS criteria for exclusion of high risk donors. There is a slight overlap of questions from the UNOS specific section and the USPHS section, but AMS did not want to omit any information from either section. A thorough review of this form's contents will be needed.

Lookup Field

Field Name	List Name
CancerSite	CancerSite

Lab Data - (Column Entry Forms)

These forms contain lab data that is collected on the APOPO form. Notes does not have the ability to dynamically add columns, therefore there will be a maximum number of columns that can be utilized for each form and for each donor. There is no additional overhead for storing extra column fields because Notes does not save the data definition in a form, rather it is saved in the template. Each form will have a comments field for recording additional information.

Form	Maximum Columns
Chemistry	50
CBC & Diff	10
Urinalysis	10
Hemodynamics/ Temperature	40
Intake/Output	10
Arterial Blood Gases	10
Medications/ Drugs	10

Lookup Field

Field Name	List Name
DrugName	Medications

Serology and Microbiology

Unlike the lab data, the Serology and Microbiology forms are fixed column forms. The Serology form has lookups for each entry and both forms will have a comments field for recording additional information.

Lookup Fields

Field Name	List Name
PostAnti-HIV1	Serology
PostAnti-HIV2	Serology
PostAnti-HTLV1	Serology
PostAnti-HTLV2	Serology
PostRPR-VDRL	Serology
PostAnti-CMV	Serology
PostHBsAg	Serology
PostAnti-HBC	Serology
PostAntiHCV	Serology
PreAnti-HIV1	Serology
PreAnti-HIV2	Serology
PreAnti-HTLV1	Serology
PreAnti-HTLV2	Serology
PreRPR-VDRL	Serology
PreAnti-CMV	Serology
PreHBsAg	Serology
PreAnti-HBC	Serology
PreAntiHCV	Serology

Cardiac Data

The Cardiac Data form contains interpretations for EKG, ECHO and Angiography. There are two fields, Drug and HeartRhythm, which were said to have lists associated with them, but AMS has not received the lists from UNOS. The Drug field could use the generic medications lookup table, however it would be more appropriate to obtain a list specific to the Cardiac Data form. There is also the capability of adding more than one drug and dosage, unlike the current AOPO form.

Pulmonary Data

The Pulmonary Data form contains interpretations for Chest X-rays and a Bronchoscopy. Chest measurements are also entered on this form. There are only two places in which to enter chest X-ray data on the AOPO form. The Pulmonary Data form is capable of recording five chest X-ray entries.

Intraoperative Management

The Intraoperative Management form is the place where users will record data pertaining to the actual surgery and removal of organs. OR teams, Medications, Blood Products and specific dates and times are entered on this form. The CDR

form specifically asks for medications given in the 24 hours prior to organ removal. That data will be collected in this section.

Lookup Fields

Field Name	List Name
BloodProducts	BloodProducts
Medications	Medications

Kidney Data

The Kidney Data form is a data intensive form. It contains all data pertaining to both the left and right kidney once they have been removed from the donor. There are three sections to this form. The first section contains data common to both kidneys. The second section is for the left kidney anatomy and the last section is for the right kidney anatomy. There are two diagrams on this form so the user can mark any abnormalities directly on the kidney diagrams.

Lookup Fields

Field Name	List Name
FlushSolution	FlushSolution
StorageSolution	StorageSolution

Heart, Lung, Pancreas and Liver Data

Each one of these forms is used after the organ has been removed from the donor. They contain organ specific information concerning the removal and storage of the organ. Each form is separate so that only the appropriate information gets sent to those whose request it.

Lookup Fields

Field Name	List Name
FlushSolution	FlushSolution
StorageSolution	StorageSolution

Intestine Data

As of September 23, 1994, AMS has not received any intestine data information.

Tissue Data

The Tissue Data form is arranged in a grid format. The user records which tissue was recovered and explains why it was not recovered in certain cases. The technician and tissue bank are recorded for each entry.

<div> <input type="button" value="Home"/> <input type="button" value="Jump"/> <input type="button" value="Print"/> <input type="button" value="Prev<"/> <input type="button" value="Next>"/> </div> <h3 style="text-align: center;">Tissue Data</h3> <p> OIS ID: 092094130712345 UNOS ID: HIT847 Donor Name: Bryan Lilley 09/22/94 </p> <table border="1"> <thead> <tr> <th>Tissue</th> <th>Recovered</th> <th>Explanation, if No</th> <th>Technician</th> <th>Tissue Bank</th> </tr> </thead> <tbody> <tr> <td>Corneas/Eyes</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Skin</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Bone/Tendon</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Saphenous Vien #</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Heart Valve</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table>					Tissue	Recovered	Explanation, if No	Technician	Tissue Bank	Corneas/Eyes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Bone/Tendon	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Saphenous Vien #	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Heart Valve	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Corneas/Eyes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																			
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																			
Bone/Tendon	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																			
Saphenous Vien #	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																			
Heart Valve	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																			
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																			

General Notes

The General Notes form is the area where users can record any other relevant information that is not covered in the forms of the Donor document. This form will be the coordinator's note-taking area.

Organ Recovery

Once the organs have been removed from the donor and placed with a recipient, the coordinator may elect to complete this form in order to have all of the necessary CDR data in one place. The Organ Recovery form is organized exactly like the last page of the CDR form. Basic questions are asked about the flush and storage solution and the disposition of the organ. Certain questions are also asked about the recipient and the recipient's center.

Lookup Fields

Field Name	List Name
TimeZone	TimeZone
LeftKIRecovered	LeftKIRecovered
RightKIRecovered	RightKIRecovered
LiverRecovered	LiverRecovered
IntestineRecovered	IntestineRecovered
PancreasRecovered	PancreasRecovered
HeartRecovered	HeartRecovered
LeftLungRecovered	LeftLungRecovered
RightLungRecovered	RightLungRecovered
RecvTeamProviderNum	provider list
FlushSolution	FlushSolution
StorageSolution	StorageSolution
PlacedBy	PlacedBy
ShareType	ShareType
DispositionCode	DispositionCode
DiscardReason	DiscardReason
RecipientCenterProvNum	provider list

Match Run Input

The Match Run Input form is where a coordinator may edit Match Run information and request a new Match Run. This form contains all of the fields in the Match Run donor record used by the UNOS Match Run program. There are three important pieces to understanding how the Match Run process will work.

- Match Run Input form
- Match Run Gateway processes
- Match Run Results form

The Match Run Gateway and Match Run Results forms are discussed in later sections.

The Match Run Input form displays the fields in the Donor document that are necessary to request a Match Run. The actual Match Run process does not start until the user initiates it by pressing the Request Match Run button located on this form.

Match Runs can produce large and unsightly outputs, especially when an "O" donor is run for a kidney match. To avoid this problem, the user will enter the maximum number of lines to be produced for display. The default number will be 300 lines.

Different Match Runs can be run if a center is a SEOPF member or a Region 6 center. The Universal Donor Match will be the default Match Run type. If a center has access to run a SEOPF, SEOPF High Grade or a Region 6 match, then they will be prompted to select which match type they want to run. The SEOPF, SEOPF High Grade and the Region 6 matches are not used for extra renal matches.

New Tray Result documents may be composed from this form if crossmatch results are available. Coordinators in centers that have individualized donor input variances will enter the appropriate information in a separate section.

Currently, the center codes which have individualized donor input variances are:

- | | | |
|-------------------------------------|------|-------------------------------------|
| <input checked="" type="checkbox"/> | NCNC | Carolina Organ Procurement Agency |
| <input checked="" type="checkbox"/> | NJTO | New Jersey Tissue & Organ Share |
| <input checked="" type="checkbox"/> | TXGC | Gulf Coast Organ Procurement Agency |
| <input checked="" type="checkbox"/> | MWOB | Midwest Organ Bank |
| <input checked="" type="checkbox"/> | TXSA | South Texas Organ Bank |
| <input checked="" type="checkbox"/> | LAOP | Louisiana Organ Procurement Agency |
| <input checked="" type="checkbox"/> | OKxx | All Oklahoma Centers |
| <input checked="" type="checkbox"/> | TXSB | Southwest Organ Bank |
| <input checked="" type="checkbox"/> | IAOP | Iowa Statewide OPO |
| <input checked="" type="checkbox"/> | NEOB | New England Organ Bank |
| <input checked="" type="checkbox"/> | VAXx | All Virginia Centers |
| <input checked="" type="checkbox"/> | OC | Organ Center |






Each input variance is explained in structured English in the Appendix. This particular appendix needs to be thoroughly reviewed by UNOS IS staff members in order to ensure that the variance variable is filled in correctly.

The Match Run donor record layout and field definitions are located in the appendix. This record is filled and then passed to the UNOS Match Run program through the VB/Notes Match Run Gateway.

Match Run Results Document

Match Run Results are imported into the OIS system through the VB/Notes Match Run Gateway. Once the Match Run Results have been imported into the system and replicated to the coordinator's mobile computer, Match Run Result documents can be accessed through a View.

The Match Run Results form consists of three main sections. The first section of the form contains identifying information about the Match Run. The second section of the form controls who can read and edit the form. The last section of the form contains the actual results of the Match Run.

OIS ID: 092094130712345		UNOS ID: HCZ001	Match Run Number: 1		
Organ: HR	Date: 03/26/1994	Time: 10:31			
Add Readers:			Reader Names:	VAFH, VAMC, John Smith/VAMV/UNOS,	
Add Authors:			Author Names:	Jill King/VAFH/UNOS, Brian Johnson/VAMC/UNOS,	
Match Run Results					

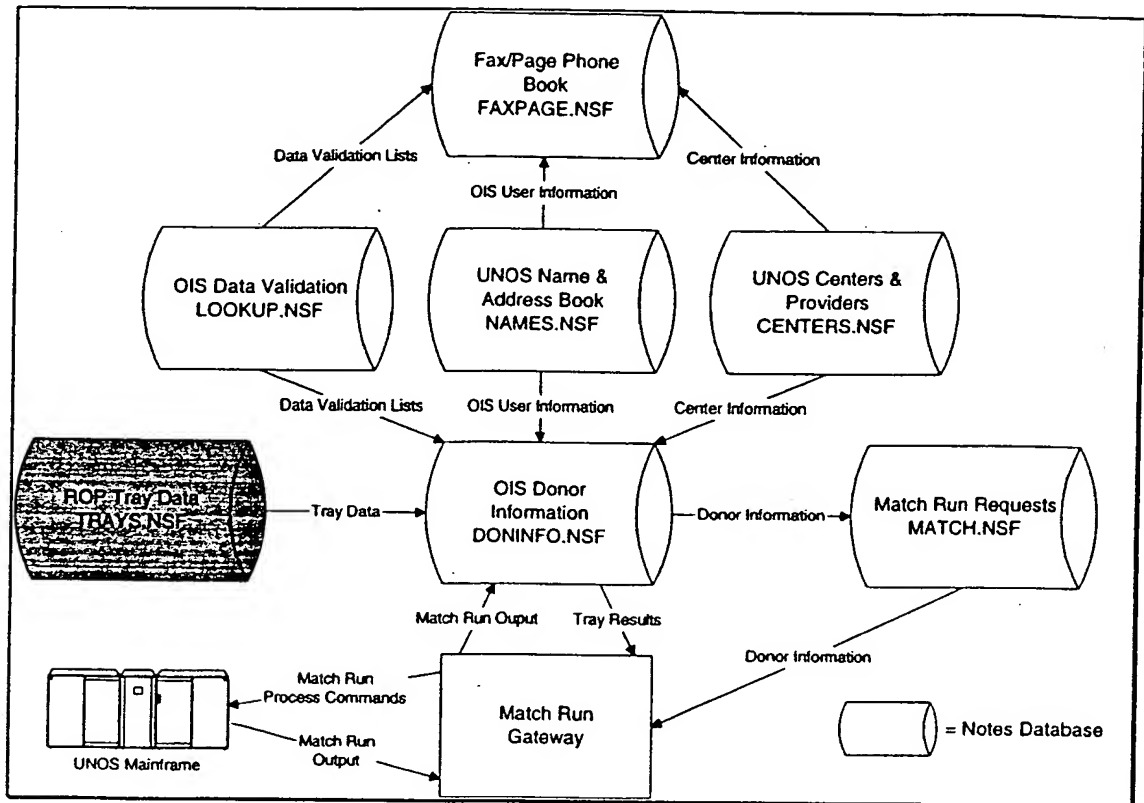
Users may compose Fax and/or Pager Notification documents from the Match Run Results document by pressing the Fax or Page buttons. Both Faxing and Paging are explained in their corresponding sections within this document.

Tray Results Document

A Tray Results document may be composed from the Match Run Input form in the Donor document. When the Trays Results document is composed, it inherits the OIS ID from the Donor document, and becomes a child to the parent Donor document. The donor name is retrieved from the parent Donor document for display purposes. Data entry on this form consists of selecting the tray name from a list, and entering values for each cell in the tray. Valid tray names are pulled from the ROP Tray Data database and cell values lists are stored in the OIS Data Validation database. The Tray Results document ensures that data entered in a Tray Result cell has a matching cell record in the ROP Tray Data database.

Tray Results						
OIS ID: 123450920941150			Donor Name: Bryan Lilley			
Tray Name: ,						
	A	B	C	D	E	F
1	,	,	,	,	,	,
2	,	,	,	,	,	,
3	,	,	,	,	,	,
4	,	,	,	,	,	,
5	,	,	,	,	,	,
6	,	,	,	,	,	,
7	,	,	,	,	,	,

ROP Tray Data



Description

This database contains ROP Tray data to be used for data validation and to build crossmatch results files used in the Match Run process. Documents in this database are records in ROP Tray data files on the UNOS mainframe. This reference data is maintained on the mainframe; periodic updates to the Notes database will be necessary. The OIS system administrator must ensure that this reference database is in sync with the mainframe files. When users compose Tray Results documents, this database provides a valid list of tray names and is used to verify that data is entered in valid cells.

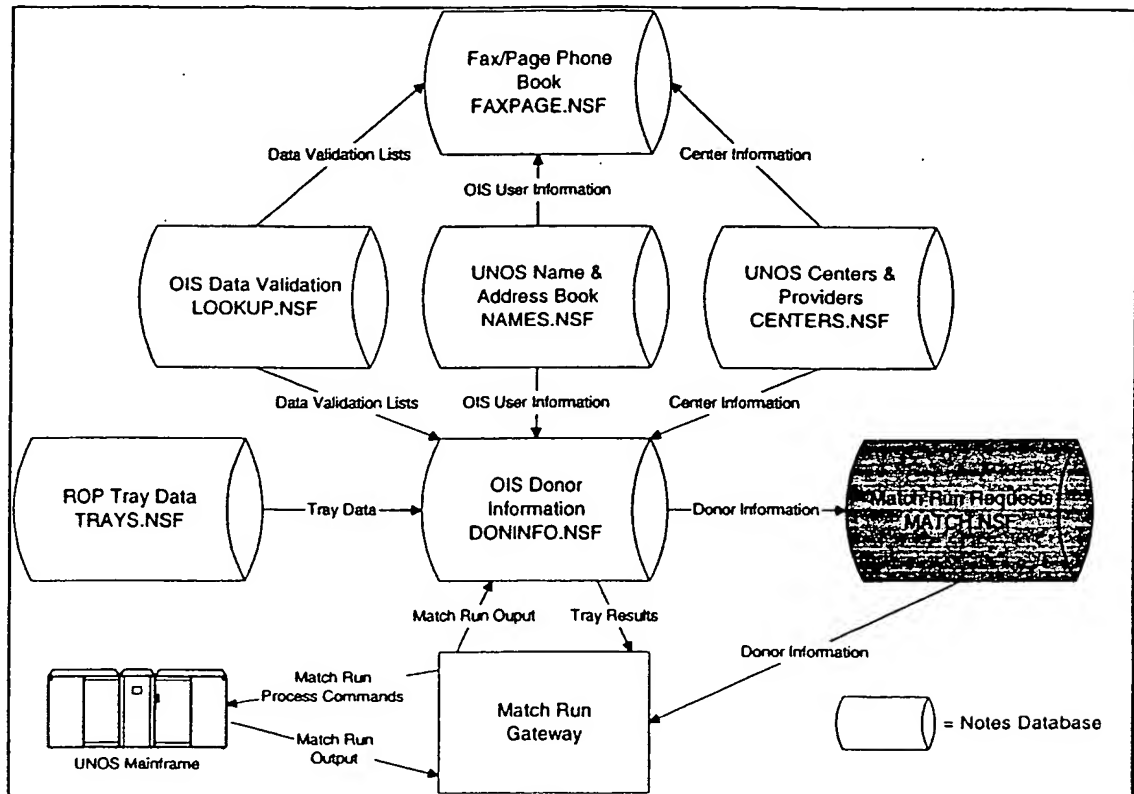
Tray Data File Record Layout

Field Name	Length	Columns
HOSP	4	1-4
ABO	2	5-6
Recipient Name	12	7-18
HICNUM	10	19-28
WELLNO	3	29-31
PK	2	32-33
CR	2	34-35
MONTH	2	36-37
YEAR	2	38-39

User Access

All users will have Reader access to this database. This database may be viewed by users for reference, but it is primarily designed for system access. Because this data is maintained on the mainframe, users may not change or enter tray data through the OIS.

Match Run Requests



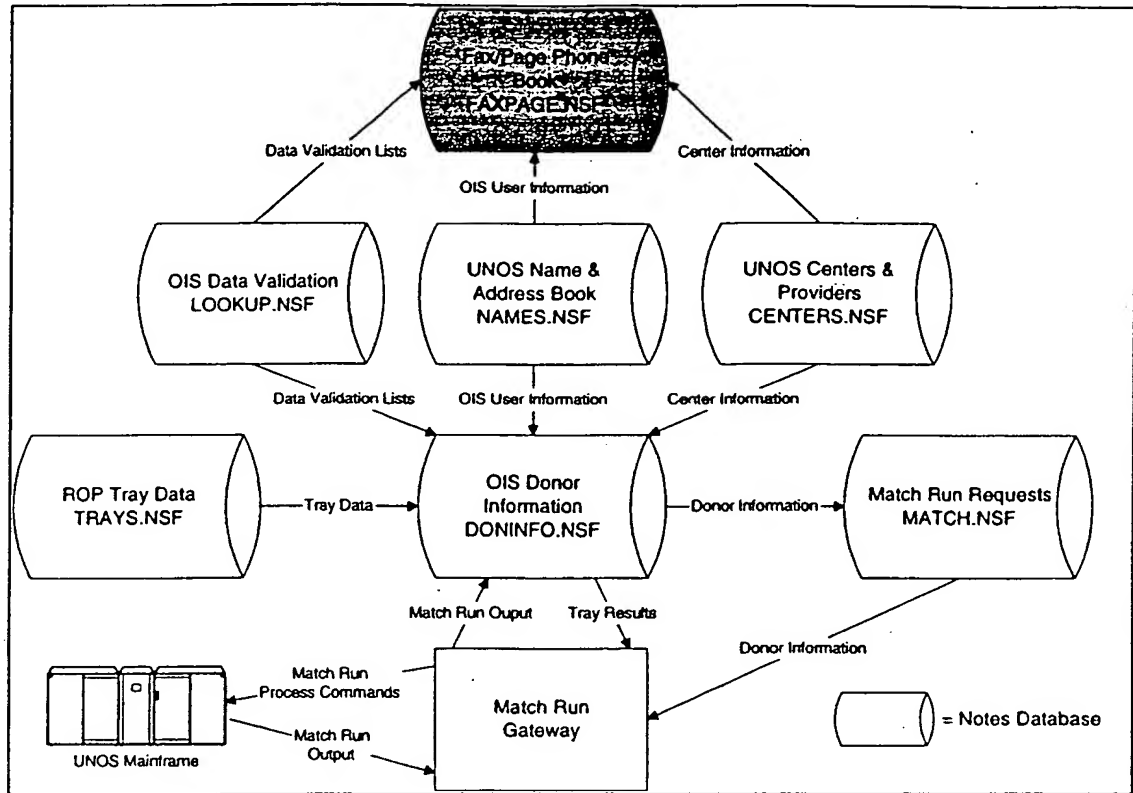
Description

The Match Run Request database holds donor information which is used for a Match Run request. When a coordinator initiates a Match Run from the field, a copy of the Donor document is sent to the Match Run Request database. This database is monitored by the VB/Notes Match Run Gateway process which initiates the Match Run process on the mainframe when a new request enters the database. Once the request has been processed, the Donor document will be moved to a Match Run Request Archive database. The structure of the Match Run Requests database is identical to the Donor Information database.

User Access

Only the Match Run Gateway and system administrators will have access to this database.

Fax/Page Phone Book



Description

The Fax/Page Phone Book database contains information for people who have registered their fax machines or pagers with the OIS system along with their corresponding fax or pager PIN numbers. This information is collected through a Contact Document which consists of Center ID, Name, Fax Number, Pager PIN Number, Voice Number, and Comments. The people in the phone book may or may not be OIS users. This database is referenced when addressing a Fax or Pager Notification document, or may be used for reference by OIS users.

User Access

Once the document is created, it may be modified by the users in the Center ID group, the author of the document, or the Organ Center users.

PAGER NOTIFICATION

The paging process allows OIS users to immediately notify people that donor information is available. There are three situations where users would use Pager Notification:

- To notify another Notes user to replicate with the server to receive the latest donor information.
- To notify another person to call into Phone Notes in order to request a fax of the latest donor information.
- To notify another person that donor information has been faxed to them.

A user may compose a Pager Notification document from the Donor Navigation form or from the Match Run Results form.

A user may address the Pager Notification document by:

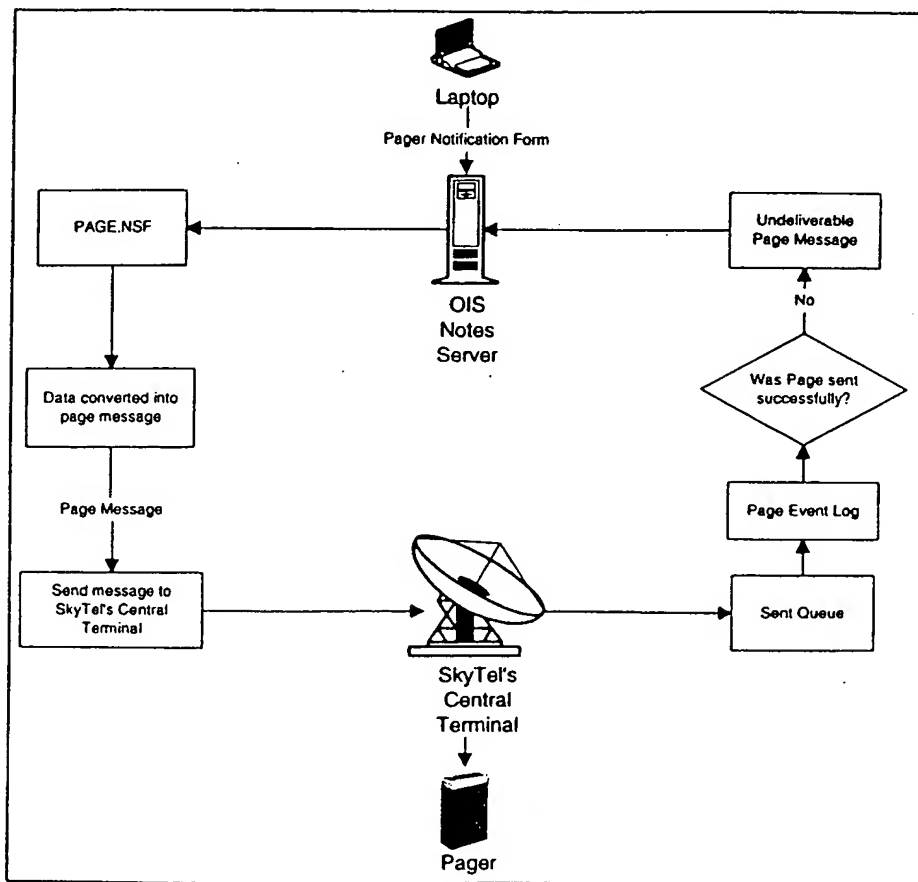
- Selecting a person from a list of people with pagers from the Fax/Page Phone Book.
- Selecting a center from a list of centers with pagers from the Center & Providers database.
- Typing in the pager PIN number directly.

A user enters a text message that may contain information such as recipient's name, recipient's position on the Match Run list and organ(s) available. The text message will be limited to the maximum number of characters supported by the SkyWord pager.

Currently, the Notes Pager Gateway is only compatible with the SkyTel Paging network. SkyTel is the leading provider of nationwide wireless messaging, reaching more than 90% of the US business population in over 11,000 cities and towns. SkyTel's SkyWord pager consists of an LCD screen suitable for displaying information on the Pager Notification document.

The Pager Notification document is sent to the pager gateway. Once the document reaches the gateway, the following occurs:

- The pager gateway will convert the data into a Page message.
- The message is sent to SkyTel's central terminal.
- SkyTel immediately broadcasts the message to the SkyWord pager that has the corresponding PIN number.
- The LCD screen on the SkyWord pager will display who sent the page and their center, Date, OIS ID, and comments.



FAXING DONOR INFORMATION

Faxing donor information provides OIS users the ability to rapidly transmit information to people even if they are not a Notes client. Users may compose Fax documents from the Donor Navigation form or from the Match Run Results form.

A user may address the Fax document by:

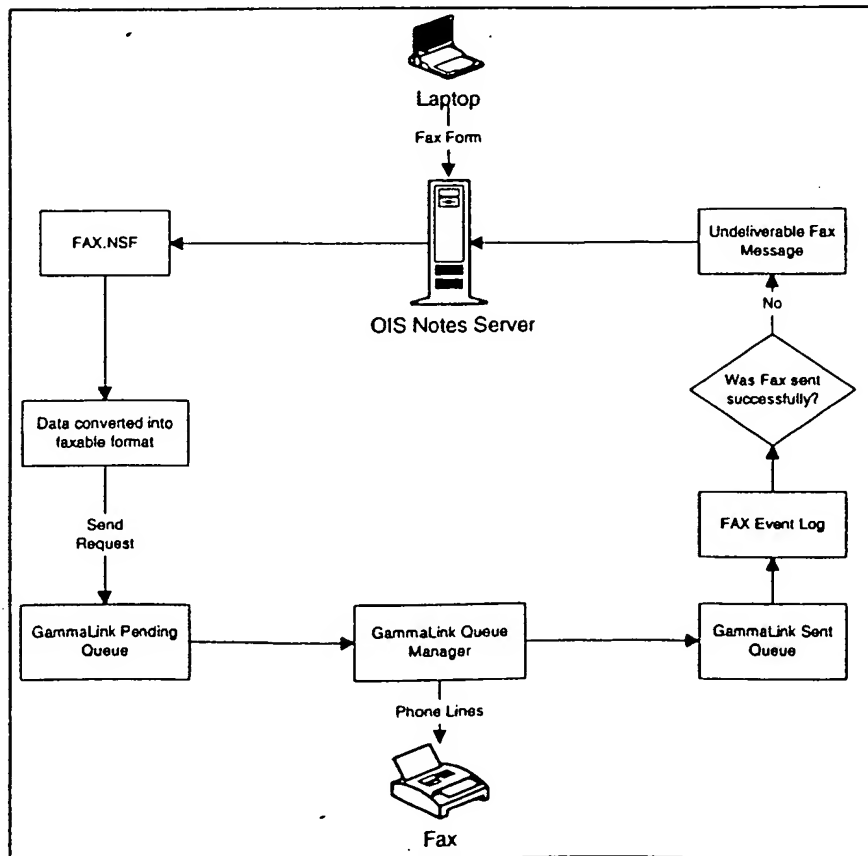
1. Selecting a person from a list of people with fax machines from the Fax/Page Phone Book.
2. Selecting a center from a list of centers with fax machines from the Center & Providers database.
3. Typing in the fax number directly.

A user enters comments that may contain information such as recipient's name, recipient's position on the Match Run list and organ(s) available. This is stored in the comments section on the fax cover page. Users will also have the ability to select only the donor information forms that they want faxed. The selected forms will be pasted onto the Fax form.

		Centers	Names	Fax
Fax Name:	Sally Jones			
Fax Number:	(703) 267-2222			
From:	Julian Marks at Center AMS			
Date:	09/22/94 11:33:30			
Comments:	John Smith 3rd on list HR			
 Sender Phone Number: (703) 267-7015				

The Fax document is sent to the fax gateway. Once the document reaches the gateway, the following occurs:

- The fax mail is sent to a special Fax.NSF mailbox.
- A cover page for each fax will be created pulling information from the Fax document and the Donor document forms.
- The fax gateway continuously checks the Fax.NSF mailbox for fax mail.
- Once mail is found, the data is converted into a TIFF file for faxing.
- A Send request is placed in the GammaLink Pending queue.
- The GammaLink Queue Manager checks the Pending queue for Send requests.
- The data is sent over the phone lines to the receiving fax machine.
- The transmission is recorded in the GammaLink Sent queue.
- The transmission is added to the Fax Event Log.
- If sending the fax is unsuccessful, then the fax is returned to the sender with a message stating that the fax was undeliverable.



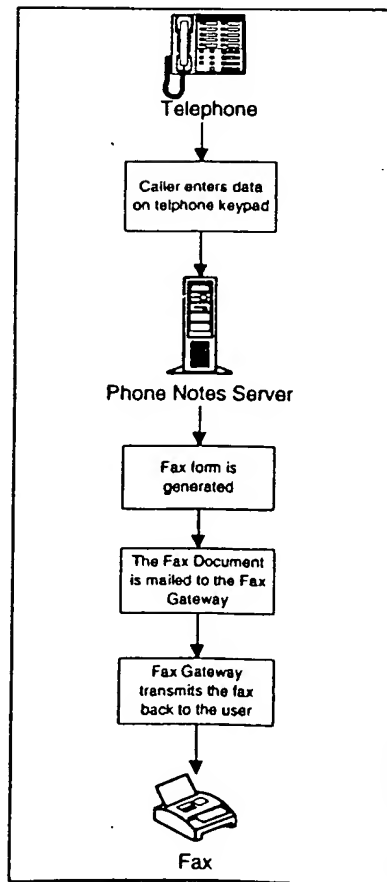
A user has the option of purchasing a fax modem for their computer and sending the information directly to another person. The user would print the donor information to the fax modem, enter the fax number, and fax it. Utilizing the fax

gateway does not require any additional hardware or software Notes Client workstations.

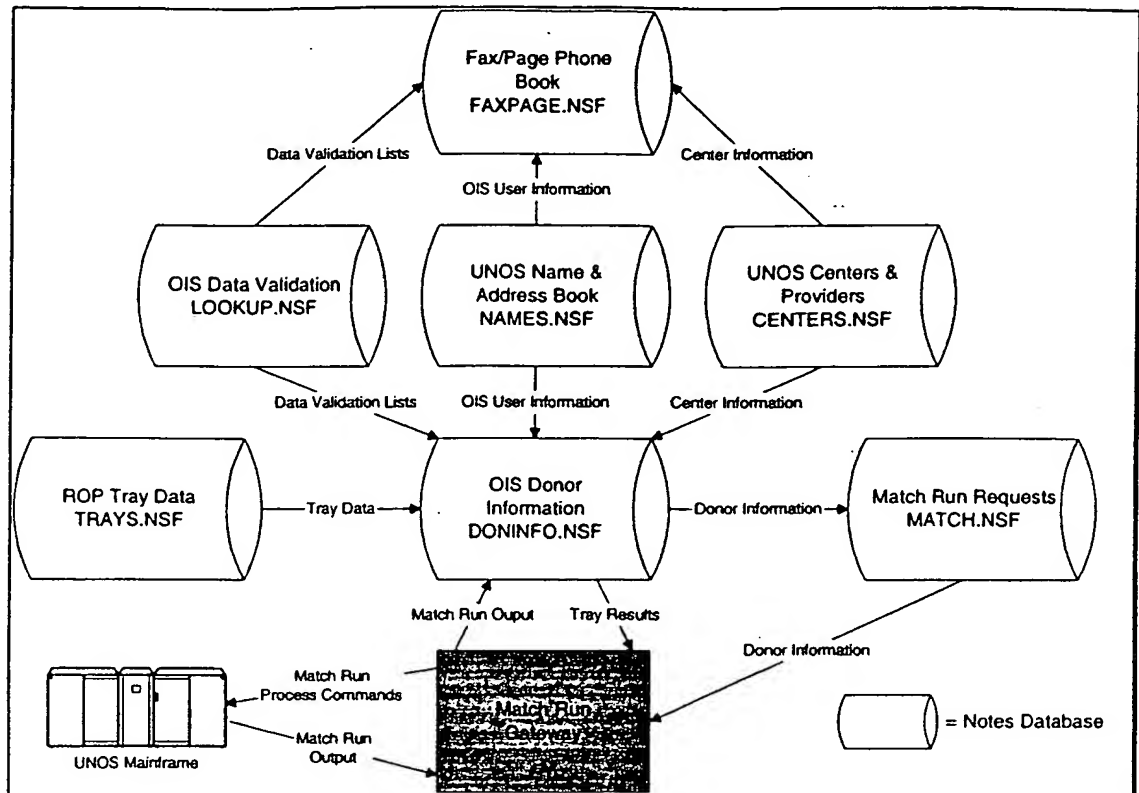
PHONE NOTES

Once a center is notified that donor information is available, a user may call from any touch-tone telephone and have the donor information faxed back to them through Phone Notes. This expands the users of the OIS system to anyone with a touch-tone telephone. The caller does not need to be a Notes user. People who wish to use the OIS Phone Notes feature must register with UNOS to receive an OIS Phone Notes user number and Personal Identification Number (PIN). A user would call the server, log into the OIS system using their user number and PIN, listen to voice prompts, and enter the OIS ID and their fax number on a telephone keypad. The donor information would then be faxed back to them.

When a user calls and enters an OIS ID, Phone Notes generates a Fax document with the donor information for the specified OIS ID. When a user keys in their fax number on their telephone keypad, the fax number is entered on the Fax document. When the user completes the call, the information is faxed to the user's fax machine, and an entry is made in the Phone Notes transaction log to record the event.



MATCH RUN GATEWAY



VB/Notes Background Process

The VB/Notes Match Run gateway will be written in Visual Basic using the VB/Link for Lotus Notes VBX to read and write Notes data. The gateway will run in Windows and mimics a standard Notes client that accesses OIS Notes server over the UNOS Pathworks network. The gateway constantly loops, performing two basic functions: checking for new Match Run requests in the Match Run Request Notes database, and checking for Match Run Results from the mainframe gateway server program.

Processing Match Run Requests

When the VB/Notes gateway detects a new Match Run request:

1. The VB/Notes gateway builds the Universal Donor Record based on the data contained in the Donor document residing in the Match Run Request database.
2. If crossmatch results are to be used, a Crossmatch Results data file is created based on the Tray Results documents that have been composed for the donor.
3. The VB/Notes gateway calls the mainframe gateway server program, passing the Universal Donor Record with the OIS ID appended to the end.
4. The Match Run Request document is moved to a Match Run Request Archive database.
5. An entry is made in the VB/Notes gateway log (Notes database).

Process Match Run Results

The VB/Notes gateway constantly monitors the shared network directory that the Match Run results will be written to. When a Match Run results file is located:

1. The Match Run results header is read to obtain key and identifying information.
2. The Donor document associated with the Match Run results is located based on the OIS ID and a Match Run Results document is created as a child of the Donor document.
3. If the import process is successful, the Match Run results file is deleted.
4. If an error occurs, the Match Run results file is forwarded to the system administrators in an urgent mail message.
5. An entry is made in the VB/Notes gateway log (Notes database).

Error Trapping

Any errors encountered by the VB/Notes gateway will be sent to the system administrator(s) in the form of an urgent mail message. The gateway will send status messages to system administrators at intervals defined by the administrator.

Match Run Results Headers

Match Run Results files from the UNOS mainframe gateway server program will be separated by organ and will have the following header:

Field Name	Length	Columns
OIS ID	15	1-15
UNOS ID	6	16-21
Organ	2	22-23
Date/Time	12	24-35
Match Run Number	2	36-37
Return Code	2	38-39
Status Message	n	40-

UNOS Development

The changes which UNOS needs to incorporate into their mainframe system are outlined in the following sections. These changes are needed in order for the Notes server and the mainframe system to share Match Run information. Without these updates to the mainframe system, the communication of Match Run output will not be possible.

UNOS Mainframe Gateway Server Program

The Mainframe Gateway Server program is the interface between the VB/Notes gateway and the Universal Donor Match Run processes. This program accepts Match Run requests from the VB/Notes Gateway, and writes the Match Run results to a shared network directory. Other requirements identified by UNOS for the Mainframe Gateway Server program are:

- Establish a network link with the VB/Notes Match Run Gateway.
- Command tracking.
- Accept crossmatch results file from the VB/Notes gateway and write the crossmatch results file with long name (UNOS ID+DATE+TIME+'.CSM') to USER\$SEOPF:[MATCH_RESULTS.TRAYS].
- Initiate OIS Universal Donor programs

Appendix

Donor Information Data Fields

OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Case Information	Case Information	CaseType	.donr cdytpe	Text	3	Valid codes	CDTYP	CDR	
Case Information	Case Information	Local	.donr dlocal	Text	1	Must be Y or N	CDTYP	CDR	
Case Information	Case Information	ReferralCallDate/Time	.donr recdt	Date/Time	8	Must be a valid date & time		CDR, AOPO	CDR only has date, but AOPO has date & time. Save date and time.
Case Information	Case Information	ReferralType		Text	15	Organ Referral Only, Tissue Referral			
Case Information	Case Information	DonorCenterName		Text	50	Tissue Referral		AOPO	
Case Information	Case Information	DonorCenterCode	DCENTER	Text	4	Center Name		AOPO	Centers database
Case Information	Case Information	UNOSID	.donr donid	Text	7	valid 4-digit center code		AOPO, MR	
Case Information	Case Information	MedRecNumber		Text	15	UNOS assigned		AOPO	
Case Information	Case Information	RecoveryDate	.donr recvdt	Date/Time	8	must be after 9/1/87 (why?)			only need recovery date, not time. Time is noted for each organ via clamp and other things
Case Information	Case Information	CoordinatorName1		Text	50	Should be later than DOB		AOPO, CDR	
Case Information	Case Information	CoordinatorPhone1		Text	20			AOPO	
Case Information	Case Information	CoordinatorName2		Text	50			AOPO	
Case Information	Case Information	CoordinatorPhone2		Text	20			AOPO	
Case Information	Case Information	AdmissionDate/Time		Date/Time	8			AOPO	
Case Information	Case Information	ArrivalDate/Time		Date/Time	8			AOPO	What is the difference between arrival and admission date/time?
Case Information	Case Information	AttendingPhysician		Text	50			AOPO	What is the difference between arrival and admission date/time?
Case Information	Case Information	ReferringPerson		Text	50			AOPO	
Case Information	Case Information	HospitalProviderNum	.donr hospprv	Text	10	Valid number	PRVDRS	CDR	
Case Information	Case Information	HospitalName	.prvdr prvname	Text	60			CDR	
Case Information	Case Information	HospCity		Text	50			AOPO	Need to build this table - assistance from UNOS
Case Information	Case Information	HospState		Text	2	Valid State abbreviation	STATE	AOPO	Need to build this table - assistance from UNOS
Case Information	Case Information	HospZip	ZIP	Text	10	5 or 10 digit		AOPO, MR	Need to build this table - assistance from UNOS
Case Information	Case Information	HospUnit		Text	25			AOPO	Need to build this table - assistance from UNOS
Case Information	Case Information	HospPhone		Text	20				Need to build this table - assistance from UNOS
Case Information	Case Information	HospFax		Text	20			AOPO	Need to build this table - assistance from UNOS
Case Information	Case Information	OPOProviderNum	.donr opold	Text	6			AOPO	Need to build this table - assistance from UNOS
Case Information	Case Information	OPOCenterCode	.donr opocmp	Text	4			CDR	Need to build this table - assistance from UNOS
Case Information	Case Information	OPOName	.prvdr prvname	Text	60			CDR	Need to build this table - assistance from UNOS
Case Information	Case Information	DonorFirstName	.donr fname	Text	15			CDR	
Case Information	Case Information	DonorLastName	.donr lname	Text	25			CDR	
Case Information	Case Information	HomeCity	.donr city	Text	30			CDR	
Case Information	Case Information	HomeState	.donr state	Text	2			CDR	
Case Information	Case Information	HomeZip	.donr zip	Text	9			CDR	
Case Information	Case Information	DatedBirth	.donr dob	Date/Time	8	valid date, must be greater than clamp date (CLAMPDT)		CDR	
Case Information	Case Information	SSN		Text	12			AOPO	

OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Donor Information	Donor Information	HomeAddress		Text	50			AOPO	
Donor Information	Donor Information	Age	.donr age	Text		2 valid range from 0 to 99 years		AOPO,CDR,MR	Can be calculated from dob, but dob is
Donor Information	Donor Information	Gender	.donr gndr	Text		1 M or F		AOPO,CDR,MR	sometimes not available. Age should be
Donor Information	Donor Information	USBorn	.donr usbrn	Text		1 valid entries are Y, N, or U		AOPO,CDR	saved in the db.
Donor Information	Donor Information	YearsInUS	.donr usyrs	Text		2 is null unless USBorn = N		AOPO,CDR	
Donor Information	Donor Information	Race	.donr race	Text		3 valid codes	RACE	AOPO,CDR	
Donor Information	Donor Information	USCitizen	.donr uscdt2	Text		valid entries are Y, N, or U.			
Donor Information	Donor Information	Etnicity	.donr hisp	Text		1 citizen is null unless USBorn = N		AOPO,CDR	
Donor Information	Donor Information	CausedDeath	.donr cod	Text		3 valid codes	DTHC	AOPO,CDR	
Donor Information	Donor Information	Height	.donr hgt	Text		5 valid range from 1 to 255 CM		AOPO,CDR	
Donor Information	Donor Information	HeightUnit		Text		C or I - used in MR too			
Donor Information	Donor Information	Weight	.donr wgt	Text		1 HGTUNIT		MR	
Donor Information	Donor Information	WeightUnit		Text		5 valid range from 0 to 200.00 KG		AOPO,CDR,MR	
Donor Information	Donor Information	OtherCauseofDeath	.donr codth	Text		1 K or L		MR	
Donor Information	Donor Information	ActiveMilitary		Text		20 is null unless COD = other		AOPO,CDR	
Donor Information	Donor Information	MechanismofDeath	.donr dthmch	Text		1 Y or N		AOPO	
Donor Information	Donor Information	CircumstancesofDeath	.donr dthcic	Text		3 valid codes	DTHM	AOPO,CDR	
Donor Information	Donor Information	ME-CoronerCase	.donr nepr1	Text		3 valid codes	DTHCM	AOPO,CDR	
Donor Information	Donor Information	MEPermission	.donr meperm1	Text		1 Y or N or U		AOPO,CDR	
Donor Information	Donor Information	MECaseNum		Text		Y or N or U, permission is null		AOPO,CDR	
Donor Information	Donor Information	Residitions-DenialReasons		Text		1 unless me case was yes		AOPO	
Donor Information	Donor Information	ME-CoronerName		Text		50		AOPO	
Donor Information	Donor Information	MEContactDate Time		Date/Time	8			AOPO	
Donor Information	Donor Information	BrainDeathDate Time1		Date/Time	8			AOPO	
Donor Information	Donor Information	BrainDeathDate Time2		Date/Time	8			AOPO	
Donor Information	Donor Information	BrainDeathMD1		Text	50			AOPO	
Donor Information	Donor Information	BrainDeathMD2		Text	50			AOPO	
Donor Information	Donor Information	BrainDeathMethodsUsed		Text	50			AOPO	
Donor Information	Donor Information	BrainDeathPronounced		Text		3 Y or N		AOPO	
Donor Information	Donor Information	Autopsy		Text		3 Y or N		AOPO	
Donor Information	Donor Information	A1		Text		2 valid list value only	AHLA	MR, AOPO	
Donor Information	Donor Information	A2		Text		2 valid list value only	AHLA	MR, AOPO	
Donor Information	Donor Information	B1		Text		2 valid list value only	BHLA	MR, AOPO	
Donor Information	Donor Information	B2		Text		2 valid list value only	BHLA	MR, AOPO	
Donor Information	Donor Information	DR1		Text		2 valid list value only	DRHLA	MR, AOPO	
Donor Information	Donor Information	DR2		Text		2 valid list value only	DRHLA	MR, AOPO	
Donor Information	Donor Information	C1		Text		2 valid list value only	DRHLA	MR, AOPO	
Donor Information	Donor Information	C2		Text		2 valid list value only	DRHLA	MR, AOPO	
Donor Information	Donor Information	ABO	.donr abo	Text		2 valid list value only	ABO	AOPO	
Donor Information	Donor Information	RH	.donr rh	Text		2 valid codes	ABO	AOPO,CDR,MR	
Donor Information	Donor Information			Text		Valid entries are +, -, or U for		AOPO,CDR,MR	
Donor Information	Donor Information			Text		2 POS, NEG or UNK		AOPO,CDR,MR	

9/22/94

OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Donor Information	Donor Information	Sub	.donr init	Text	2	Valid entries are Y or N		AOPO	
Donor Information	Infection	Clinical Infection	.donr init	Text	1	Valid entries are Y or N		CDR	
Donor Information	Infection	Blood Infection	.donr bidinf	Text	1	Valid entries are Y or N		CDR	
Donor Information	Infection	Blood Confirmed	.donr bloodconf	Text	1	Valid entries are Y or N		CDR	
Donor Information	Infection	Pulmonary Infection	.donr pulinf	Text	1	Valid entries are Y or N		CDR	
Donor Information	Infection	Pulmonary Confirmed	.donr pulconf	Text	1	Valid entries are Y or N		CDR	
Donor Information	Infection	Urine Infection	.donr urinf	Text	1	Valid entries are Y or N		CDR	
Donor Information	Infection	Urine Confirmed	.donr urconf	Text	1	Valid entries are Y or N		CDR	
Donor Information	Infection	Other Infection	.donr othinf	Text	1	Valid entries are Y or N		CDR	
Donor Information	Infection	Other Infection Text	.donr othinfht	Text	1	Valid entries are Y or N		CDR	
Donor Information	Infection	Other Infection Confirmed	.donr othinfconf	Text	1	Valid entries are Y or N		CDR	
Consent & Admission	Admission Course/Comments	Admission Course/Comments		Text	500	1 contains text		AOPO	
Consent & Admission	Admission Course/Comments	Chest Compressions		Text	50	1 Y or N		AOPO	
Consent & Admission	Admission Course/Comments	Compression Time		Text	50	1 Y or N		AOPO	
Consent & Admission	Admission Course/Comments	OR Procedure		Text	50	1 Y or N		AOPO	
Consent & Admission	Admission Course/Comments	Admin + C634 OR Comments		Text	50	1 Y or N		AOPO	
Consent & Admission	Admission Course/Comments	Defibrillation		Text	50	1 Y or N		AOPO	
Consent & Admission	Admission Course/Comments	Cardiac Respiratory Arrest		Text	50	1 Y or N		AOPO	
Consent & Admission	Admission Course/Comments	Cardiac Arrest Down Time		Text	50	1 Y or N		AOPO	
Consent & Admission	Admission Course/Comments	Defibrillation Comments		Text	50	1 Y or N		AOPO	
Consent & Admission	Admission Course/Comments	Assessment Comments		Memo	0			AOPO	
Consent & Admission	Consent Information	Approached By	.donr apprcht	Text	3	valid codes	APRC	AOPO, CDR	
Consent & Admission	Consent Information	Approached By Other	.donr apprchoth	Text	20	is null unless approachedBy =		AOPO, CDR	
Consent & Admission	Consent Information	Discussion NOK	.donr kindisc	Text	1	Y or N		AOPO, CDR	
Consent & Admission	Consent Information	Permission NOK	.donr kinpermt	Text	1	Y or N		AOPO, CDR	
Consent & Admission	Consent Information	Tissue Transplant	.donr tiss	Text	1	Y or N or U		AOPO, CDR	
Consent & Admission	Consent Information	Research Consent		Text	1	Y or N		AOPO	
Consent & Admission	Consent Information	Donor Card		Text	1	Y or N or U		AOPO	
Consent & Admission	Consent Information	Consent Time		Date/Time	8	only time		AOPO	show only time
Consent & Admission	Consent Information	NOK Name		Text	50			AOPO	
Consent & Admission	Consent Information	NOK Address		Text	50			AOPO	
Consent & Admission	Consent Information	NOK Telephone		Text	15			AOPO	
Consent & Admission	Consent Information	NOK Relationship		Text	30		RLTYP	AOPO	
Consent & Admission	Consent Information	Funeral Home		Text	50			AOPO	
Consent & Admission	Consent Information	Tissue Bank Name		Text	50			AOPO	
Consent & Admission	Consent Information	Tissue Bank Coordinator		Text	50			AOPO	
Consent & Admission	Consent Information	Kidney Request	.donr kicreq	Text	1	Y or N		AOPO, CDR	
Consent & Admission	Consent Information	Liver Request	.donr liverreq	Text	1	Y or N		AOPO, CDR	
Consent & Admission	Consent Information	Intestine Request	.donr increq	Text	1	Y or N		AOPO, CDR	

OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Consent & Admission	Consent Information	PancraasRequest	.donr pacreq	Text		Y or N		APO, CDR	
Consent & Admission	Consent Information	HeartRequest	.donr hcreq	Text		Y or N		APO, CDR	
Consent & Admission	Consent Information	LungRequest	.donr lcreq	Text		Y or N		APO, CDR	
Consent & Admission	Consent Information	TissueRequest	.donr tcreq	Text		Y or N		APO, CDR	
Consent & Admission	Consent Information	KidneyReqReason	.donr kireqreas	Text		25 null unless request = No		APO, CDR	
Consent & Admission	Consent Information	LiverReqReason	.donr lireqreas	Text		25 null unless request = No		APO, CDR	
Consent & Admission	Consent Information	IntestineReqReason	.donr inireqreas	Text		25 null unless request = No		APO, CDR	
Consent & Admission	Consent Information	PancraasReqReason	.donr pareqreas	Text		25 null unless request = No		APO, CDR	
Consent & Admission	Consent Information	HeartReqReason	.donr hreqreas	Text		25 null unless request = No		APO, CDR	
Consent & Admission	Consent Information	LungReqReason	.donr lureqreas	Text		25 null unless request = No		APO, CDR	
Consent & Admission	Consent Information	TissueReqReason	.donr tireqreas	Text		25 null unless request = No		APO, CDR	
Consent & Admission	Consent Information	KidneyObtained		Text		Y or N		APO	
Consent & Admission	Consent Information	LiverObtained		Text		Y or N		APO	
Consent & Admission	Consent Information	IntestineObtained		Text		Y or N		APO	
Consent & Admission	Consent Information	PancraasObtained		Text		Y or N		APO	
Consent & Admission	Consent Information	HeartObtained		Text		Y or N		APO	
Consent & Admission	Consent Information	LungObtained		Text		Y or N		APO	
Consent & Admission	Consent Information	TissueObtained		Text		Y or N		APO	
Consent & Admission	Consent Information	KidneyObtainedReason	.donr klobireas	Text		5 Valid codes only	OCNS	APO, CDR	
Consent & Admission	Consent Information	LiverObtainedReason	.donr lobireas	Text		5 Valid codes only	OCNS	APO, CDR	
Consent & Admission	Consent Information	IntestineObtainedReason	.donr inobireas	Text		5 Valid codes only	OCNS	APO, CDR	
Consent & Admission	Consent Information	PancraasObtainedReason	.donr padobireas	Text		5 Valid codes only	OCNS	APO, CDR	
Consent & Admission	Consent Information	HeartObtainedReason	.donr hobireas	Text		5 Valid codes only	OCNS	APO, CDR	
Consent & Admission	Consent Information	LungObtainedReason	.donr lubireas	Text		5 Valid codes only	OCNS	APO, CDR	
Consent & Admission	Consent Information	TissueObtainedReason	.donr tibireas	Text		5 Valid codes only	OCNS	APO, CDR	
Initial Physical Assessment	Initial Physical Assessment	AsmptCompletionDate Time		Date/Time	8			APO	
Initial Physical Assessment	Initial Physical Assessment	Endotracheal		Text		1 Valid entries are Y or N		APO	Pulmonary Tubes
Initial Physical Assessment	Initial Physical Assessment	Tracheostomy		Text		1 Valid entries are Y or N		APO	Pulmonary Tubes
Initial Physical Assessment	Initial Physical Assessment	LeftChestTube		Text		1 Valid entries are Y or N		APO	Pulmonary Tubes
Initial Physical Assessment	Initial Physical Assessment	NumberofLeftChestTubes		Text	10			APO	Pulmonary Tubes
Initial Physical Assessment	Initial Physical Assessment	RightChestTube		Text		1 Valid entries are Y or N		APO	Pulmonary Tubes
Initial Physical Assessment	Initial Physical Assessment	NumberofRightChestTubes		Text	10			APO	Pulmonary Tubes
Initial Physical Assessment	Initial Physical Assessment	SizeEndotrachealTube		Text				APO	Pulmonary Tubes
Initial Physical Assessment	Initial Physical Assessment	BSEqual		Text		5 Valid entries are Y or N		APO	Breath Sounds
Initial Physical Assessment	Initial Physical Assessment	BSAbsentLeft		Text		1 Valid entries are Y or N		APO	Breath Sounds
Initial Physical Assessment	Initial Physical Assessment	BSWheezes		Text		1 Valid entries are Y or N		APO	Breath Sounds
Initial Physical Assessment	Initial Physical Assessment	BSClear		Text		1 Valid entries are Y or N		APO	Breath Sounds
Initial Physical Assessment	Initial Physical Assessment	BSRhaleft		Text		1 Valid entries are Y or N		APO	Breath Sounds
Initial Physical Assessment	Initial Physical Assessment	BSRhaleft		Text		1 Valid entries are Y or N		APO	Breath Sounds
Initial Physical Assessment	Initial Physical Assessment	PACathLine		Text		1 Valid entries are Y or N		APO	Cardiovascular Lines
Initial Physical Assessment	Initial Physical Assessment	CVLine		Text		1 Valid entries are Y or N		APO	Cardiovascular Lines
Initial Physical Assessment	Initial Physical Assessment	ArterialLine		Text		1 Valid entries are Y or N		APO	Cardiovascular Lines
Initial Physical Assessment	Initial Physical Assessment	CVHeartRhythm		Text		Valid entries are regular or irregular		APO	Cardiovascular Heart Rhythm
Initial Physical Assessment	Initial Physical Assessment	CVHeartTones		Text		Valid entries are normal, murmur, rub		APO	Cardiovascular Heart Tones
Initial Physical Assessment	Initial Physical Assessment	CVPulses		Text	10	Present or Absent		APO	Cardiovascular Heart Periph. Pulses
Initial Physical Assessment	Initial Physical Assessment	CVPulses Type		Text	2, 1, 2, 3, 4			APO	Cardiovascular Heart Periph. Pulses
Initial Physical Assessment	Initial Physical Assessment	CVEdema		Text		Present or Absent		APO	Cardiovascular Heart Periph. Edema
Initial Physical Assessment	Initial Physical Assessment	CVEdema Type		Text	2, 1, 2, 3, 4			APO	Cardiovascular Heart Periph. Edema
Initial Physical Assessment	Initial Physical Assessment	SunColor		Text	10	Normal, Pale or Cyanotic		APO	Inguenatory

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OIS Database Elements

Form Name	Functional Area	Noise Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Medical/Social History	Medical/Social History	USPHS1Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS2Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS3Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS4Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS5Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS6Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS7Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS8Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS9Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS10Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS11Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS12Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS13Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS14Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS15Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS16Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS17Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS18Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS19Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS20Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS21Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS22Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS23Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS24Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS25Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS26Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS27Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS28Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS29Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS30Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS31Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS32Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS33Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	USPHS34Comment		Text	50			AOPO	
Medical/Social History	Medical/Social History	MedSocComments		Text	500			AOPO	
Chemistry	Lab Data	FinalCreatinine	.dorr creat	Text	10	valid range from 0.1 to 50.0 mg/d		AOPO.CDR	Final
Chemistry	Lab Data	FinalBUN	.dorr bun	Text	10	valid range from 1.0 to 150.0 mg/d		AOPO.CDR	Final
Chemistry	Lab Data	FinalCreatinineClearance	.dorr creatclr	Text	10	valid range from 1.0 to 200 ml/min		CDR	Final
Chemistry	Lab Data	FinalTotalBilirubin	.dorr tbili	Text	10	valid range from 0.1 to 87.0 mg/d		CDR	Final
Chemistry	Lab Data	FinalSGOT-AST	.dorr sgpt	Text	10	valid range from 1.0 to 36000.0 u/ml		AOPO.CDR	Final
Chemistry	Lab Data	FinalSGPT-ALT	.dorr sgptl	Text	10	valid range from 1.0 to 50000.0 u/ml		AOPO.CDR	Final
Chemistry	Chemistry	ChemDate		Date/Time	8			AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	ChemTime		Text	5			AOPO	Admit, Final and many columns in between

OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Chemistry	Chemistry	Na+		Text	10	Range between 140-160		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	K+		Text	10	Range between 3.5-5.5		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	Cl-		Text	10	Range between 96-115		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	CO2		Text	10			AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	BUN		Text	10	<20		CDR & AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	Creatinine		Text	10	<1.5		CDR & AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	Glucose		Text	10	65-150		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	Calcium		Text	10	8.5-10.5		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	Phosphorus		Text	10	1.8-2.6		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	Bilirubin(tot/dlr)		Text	10			AOPO,CDR	Admit, Final and many columns in between
Chemistry	Chemistry	SGOT/AST		Text	10	Range between 0-40		AOPO,CDR	Admit, Final and many columns in between
Chemistry	Chemistry	SGPT/ALT		Text	10	Range between 5-35		AOPO,CDR	Admit, Final and many columns in between
Chemistry	Chemistry	GGT		Text	10	Range between 17-35		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	Alb/Tot Pro		Text	10			AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	Mp/Cholest		Text	10			AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	AlkPhos		Text	10	Range between 45-110		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	LDH		Text	10	Range between 90-250		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	PT		Text	10	Range between 11-15		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	PTT		Text	10	Range between 24-38		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	Amylase		Text	10	Range between 23-851		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	Uptase		Text	10	Range between 0-80		AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	CreatinineClearance		Text	10			AOPO	Admit, Final and many columns in between
Chemistry	Chemistry	CommentsOnResults		Text	50			AOPO	Admit, Final and many columns in between
Urinalysis	Urinalysis	URDate		Date/Time	8			AOPO	Initial and final (only 2 columns on AOPO)
Urinalysis	Urinalysis	URTime		Text	5			AOPO	Initial and final (only 2 columns on AOPO)
Urinalysis	Urinalysis	URColor		Text	15			AOPO	Initial and final (only 2 columns on AOPO)
Urinalysis	Urinalysis	URAppearance		Text	15			AOPO	Initial and final (only 2 columns on AOPO)
Urinalysis	Urinalysis	URpH		Text	10			AOPO	Initial and final (only 2 columns on AOPO)

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OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Microbiology	Microbiology	RURaterResults		Text	20			AOPO	24hr, 48hr and Final column headings
Microbiology	Microbiology	LRaterResults		Text	20			AOPO	24hr, 48hr and Final column headings
Microbiology	Microbiology	KidneyBasinResults		Text	20			AOPO	24hr, 48hr and Final column headings
Microbiology	Microbiology	MBOther1		Text	20			AOPO	24hr, 48hr and Final column headings
Microbiology	Microbiology	MBOther2		Text	20			AOPO	24hr, 48hr and Final column headings
Microbiology	Microbiology	MBComments		Text	250			AOPO	24hr, 48hr and Final column headings
Hemodynamics/Temperature	Hemodynamics/Temperature	HemoDate		Date/Time	8			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	HemoTime		Text	5			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	AverageBP		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	HeartRate		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	HighBP		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	HighBPPDuration		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	LowBP		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	LowBPPDuration		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	HemoCVP		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	PA		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	PAWP		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	CO/CI		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	TEMP		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	IndotropesVasopressors		Text	10			AOPO	Admit and at least 7 other columns
Hemodynamics/Temperature	Hemodynamics/Temperature	HemoDoseage		Text	10			AOPO	Admit and at least 7 other columns
Intake/Output	Intake/Output	IODate		Date/Time	8			AOPO	
Intake/Output	Intake/Output	IO+C293Time		Text	5			AOPO	
Intake/Output	Intake/Output	IntakeCrystalloid/AmI		Text	15			AOPO	
Intake/Output	Intake/Output	IntakeColloidAmI		Text	15			AOPO	
Intake/Output	Intake/Output	IntakeTotalBlood/Products		Text	15			AOPO	
Intake/Output	Intake/Output	Intake24hrTotal		Text	15			AOPO	
Intake/Output	Intake/Output	IntakeHourlyAvg		Text	15			AOPO	
Intake/Output	Intake/Output	Output24hrUrine		Text	15			AOPO	
Intake/Output	Intake/Output	OutputHourlyAvg		Text	15			AOPO	
Intake/Output	Intake/Output	OutputOtherAmI/Non-Urine		Text	15			AOPO	
Intake/Output	Intake/Output	Output24hrTotalAI		Text	15			AOPO	
Intake/Output	Intake/Output	OutputLowestUOPPerhr		Text	15			AOPO	
Intake/Output	Intake/Output	OutputLowestDuration		Text	15			AOPO	
Arterial Blood Gases	Arterial Blood Gases	ABGDate/Time		Date/Time	8			AOPO	
Arterial Blood Gases	Arterial Blood Gases	ABGpH		Text	10			AOPO	
Arterial Blood Gases	Arterial Blood Gases	PCO2		Text	10			AOPO	
Arterial Blood Gases	Arterial Blood Gases	P02		Text	10			AOPO	
Arterial Blood Gases	Arterial Blood Gases	HCO3		Text	10			AOPO	
Arterial Blood Gases	Arterial Blood Gases	O2Sat		Text	10			AOPO	
Arterial Blood Gases	Arterial Blood Gases	FIO2		Text	10			AOPO	
Arterial Blood Gases	Arterial Blood Gases	Rate		Text	10			AOPO	
Arterial Blood Gases	Arterial Blood Gases	TV		Text	10			AOPO	
Arterial Blood Gases	Arterial Blood Gases	PEEP		Text	10			AOPO	
Arterial Blood Gases	Arterial Blood Gases	PIP		Text	10			AOPO	
Medications	Medications - 24 hours before cross clamp	24hrAntiarhythmics	.donr antiarr	Text	1Y or N or U			CDR	
Medications	Medications - 24 hours before cross clamp	24hrAnticonvulsants	.donr anticonv	Text	1Y or N or U			CDR	

OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Medications	Medications - 24 hours before	24hAntiHypertensives	.donr antiHyp	Text	1	Y or N or U		CDR	
Medications	Medications - 24 hours before	24hAntibiotics	.donr antibio	Text	1	Y or N or U		CDR	
Medications	Medications - 24 hours before	24hVasodilators	.donr vasodi	Text	1	Y or N or U		CDR	
Medications	Medications - 24 hours before	24hVasopressors	.donr vasop	Text	1	Y or N or U		CDR	
Medications	Medications - 24 hours before	24hDopamine	.donr dopa	Text	1	Y or N or U		CDR	
Medications	Medications - 24 hours before	24hDobutamine	.donr dobut	Text	1	Y or N or U		CDR	
Medications	Medications - 24 hours before	24hOtherMedication	.donr othmed	Text	1	Valid entries are Y or N		CDR	
Medications	Medications - 24 hours before	24hOtherMedicationName	.donr othmedtxt	Text	1	Null unless other meds yes		CDR	
Medications	Medications - 24 hours before	PreTreatment	.donr preat	Text	1	Valid entries are Y or N or U		CDR	
Medications	PreTreatment	SteroidsPT	.donr plster	Text	1	Valid entries are Y or N or U		CDR	
Medications	PreTreatment	DiureticsPT	.donr pldur	Text	1	Valid entries are Y or N or U		CDR	
Medications	PreTreatment	ThyroxinePT	.donr pthyrl	Text	1	Valid entries are Y or N or U		CDR	
Medications	PreTreatment	HeparinPT	.donr phep	Text	1	Valid entries are Y or N or U		CDR	
Medications	PreTreatment	OtherPreTreatment	.donr ploth	Text	1	Valid entries are Y or N		CDR	
Medications	PreTreatment	OtherPreTreatmentText	.donr plothtxt	Text	10	Null unless preTreatment is Y		CDR	
Medications	Medications/Other Drugs	MedStartDate/Time		Date/Time	8			AOPO	
Medications	Medications/Other Drugs	MedName		Text	35			AOPO	
Medications	Medications/Other Drugs	MedDose		Text	15			AOPO	
Medications	Medications/Other Drugs	MedStopDate/Time		Date/Time	8			AOPO	
Medications	Medications/Other Drugs	MedPeakDose		Text	15			AOPO	
Medications	Medications/Other Drugs	MedPeakDoseDuration		Text	15			AOPO	
Cardiac Data	Cardiac Data	EKGDate/Time		Date/Time	8			AOPO	
Cardiac Data	Cardiac Data	EKGInterpretation		Text	50			AOPO	
Cardiac Data	Cardiac Data	EKGConsultingPhysician		Text	50			AOPO	
Cardiac Data	Cardiac Data	ECHODate/Time		Date/Time	8			AOPO	
Cardiac Data	Cardiac Data	ECHInterpretation		Text	50			AOPO	
Cardiac Data	Cardiac Data	E/EF		Text	15			AOPO	
Cardiac Data	Cardiac Data	CardiacCVP		Text	15			AOPO	
Cardiac Data	Cardiac Data	BP1		Text	15			AOPO	
Cardiac Data	Cardiac Data	HR		Text	15			AOPO	
Cardiac Data	Cardiac Data	HeartRhythm		Text	15	list box		AOPO	
Cardiac Data	Cardiac Data	Pressors		Text	5			AOPO	
Cardiac Data	Cardiac Data	DrugName		Text	30	list		AOPO	
Cardiac Data	Cardiac Data	CardiacDose		Text	25	can be many		AOPO	
Cardiac Data	Cardiac Data	ECHOConsultingPhysician		Text	50			AOPO	

OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Cardiac Data	Cardiac Data	ANGIODateTime		Date/Time	8			AOPO	
Cardiac Data	Cardiac Data	ANGIOInterpretation		Text	50			AOPO	
Cardiac Data	Cardiac Data	ANGIOConsultingPhysician		Text	50			AOPO	
Cardiac Data	Cardiac Data	BP2		Text	15			AOPO	
Pulmonary Data	Pulmonary Data	CXR1Date Time		Date/Time	8			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	CXR1Interpretation/Comment		Text	50			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	ChangeFromPrevious1		Text	1			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	CXR2Date Time		Date/Time	8			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	CXR2Interpretation/Comment		Text	50			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	ChangeFromPrevious2		Text	1			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	CXR3Date Time		Date/Time	8			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	CXR3Interpretation/Comment		Text	50			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	ChangeFromPrevious3		Text	1			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	CXR4Date Time		Date/Time	8			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	CXR4Interpretation/Comment		Text	50			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	ChangeFromPrevious4		Text	1			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	CXR5Date Time		Date/Time	8			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	CXR5Interpretation/Comment		Text	50			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	ChangeFromPrevious5		Text	1			AOPO	Chest XRay
Pulmonary Data	Pulmonary Data	MeasurementUnit		Text	5			AOPO	
Pulmonary Data	Pulmonary Data	RLungLength		Text	10			AOPO	
Pulmonary Data	Pulmonary Data	LLungLength		Text	10			AOPO	
Pulmonary Data	Pulmonary Data	AorticKnobWidth		Text	10			AOPO	
Pulmonary Data	Pulmonary Data	DiaphragmWidth		Text	10			AOPO	
Pulmonary Data	Pulmonary Data	ChestCirc/landmark		Text	10			AOPO	
Pulmonary Data	Pulmonary Data	DistRCPAtoLCPA		Text	10			AOPO	
Pulmonary Data	Pulmonary Data	TotalLungCapacity		Text	10			AOPO	
Pulmonary Data	Pulmonary Data	VitalCapacity		Text	10			AOPO	
Pulmonary Data	Pulmonary Data	Comments		Text	250			AOPO	
Pulmonary Data	Pulmonary Data	BronchoDate Time		Date/Time	8			AOPO	
Pulmonary Data	Pulmonary Data	BronchoConsultingPhysician		Text	50			AOPO	
Pulmonary Data	Pulmonary Data	Bronchointerpretation		Text	50			AOPO	
Intraoperative Management	Intraoperative Management	OREntranceDate Time		Date/Time	8			AOPO	
Intraoperative Management	Intraoperative Management	IncisionDate Time		Date/Time	8			AOPO	
Intraoperative Management	Intraoperative Management	ClampDate		Date/Time	8			AOPO	
Intraoperative Management	Intraoperative Management	ORExpitDate Time		Date/Time	8			AOPO	
Intraoperative Management	Intraoperative Management	AverageBP		Text	10			AOPO	
Intraoperative Management	Intraoperative Management	LowBP		Text	10			AOPO	
Intraoperative Management	Intraoperative Management	LowBPDuration		Text	10			AOPO	
Intraoperative Management	Intraoperative Management	HighBP		Text	10			AOPO	
Intraoperative Management	Intraoperative Management	HighBPDuration		Text	10			AOPO	

OIS Database Elements

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Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Intraoperative Management	Intraoperative Management	AverageHR		Text	10			APO	
Intraoperative Management	Intraoperative Management	LowHR		Text	10			APO	
Intraoperative Management	Intraoperative Management	LowHRDuration		Text	10			APO	
Intraoperative Management	Intraoperative Management	HighHR		Text	10			APO	
Intraoperative Management	Intraoperative Management	HighHRDuration		Text	10			APO	
Intraoperative Management	Intraoperative Management	AverageUrineOutput		Text	10			APO	
Intraoperative Management	Intraoperative Management	LastHourUrineOutput		Text	10			APO	
Intraoperative Management	Intraoperative Management	TotalUrineOutput		Text	10			APO	
Intraoperative Management	Intraoperative Management	Heparin		Text	1	Y or N		APO	cc/hr
Intraoperative Management	Intraoperative Management	HeparinTimeGiven		Text	5			APO	cc
Intraoperative Management	Intraoperative Management	HeparinDose		Text	15			APO	cc
Intraoperative Management	Intraoperative Management	Thorazine		Text	1	Y or N		APO	
Intraoperative Management	Intraoperative Management	ThorazineTimeGiven		Text	5			APO	
Intraoperative Management	Intraoperative Management	ThorazineDose		Text	15			APO	
Intraoperative Management	Intraoperative Management	Mannitol		Text	1	Y or N		APO	
Intraoperative Management	Intraoperative Management	MannitolTimeGiven		Text	5			APO	
Intraoperative Management	Intraoperative Management	MannitolDose		Text	15			APO	
Intraoperative Management	Intraoperative Management	Last		Text	1	Y or N		APO	
Intraoperative Management	Intraoperative Management	LastTimeGiven		Text	5			APO	
Intraoperative Management	Intraoperative Management	LastDose		Text	15			APO	
Intraoperative Management	Intraoperative Management	Solmedrol		Text	1	Y or N		APO	
Intraoperative Management	Intraoperative Management	SolmedrolTimeGiven		Text	5			APO	
Intraoperative Management	Intraoperative Management	SolmedrolDose		Text	15			APO	
Intraoperative Management	Intraoperative Management	OtherMed1		Text	1	Y or N		APO	
Intraoperative Management	Intraoperative Management	OtherMed1Name		Text	20			APO	
Intraoperative Management	Intraoperative Management	OtherMed1TimeGiven		Text	5			APO	
Intraoperative Management	Intraoperative Management	OtherMed1Dose		Text	15			APO	
Intraoperative Management	Intraoperative Management	OtherMed2		Text	1	Y or N		APO	
Intraoperative Management	Intraoperative Management	OtherMed2Name		Text	20			APO	
Intraoperative Management	Intraoperative Management	OtherMed2TimeGiven		Text	5			APO	
Intraoperative Management	Intraoperative Management	OtherMed2Dose		Text	15			APO	
Intraoperative Management	Intraoperative Management	MgtVasodilators		Text	1	Y or N		APO	
Intraoperative Management	Intraoperative Management	MgtVasopressors		Text	1	Y or N		APO	
Intraoperative Management	Intraoperative Management	Drug1		Text	20			APO	
Intraoperative Management	Intraoperative Management	Drug1Time		Text	20			APO	
Intraoperative Management	Intraoperative Management	Drug1Dose		Text	20			APO	
Intraoperative Management	Intraoperative Management	BloodProduct1		Text	1	Y or N		APO	
Intraoperative Management	Intraoperative Management	BloodProductType1		Text	20		yes	APO	
Intraoperative Management	Intraoperative Management	BloodProductVolume1		Text	20			APO	
Intraoperative Management	Intraoperative Management	MgtORComments		Memo	0			APO	
Intraoperative Management	Intraoperative Management	BloodProduct2		Text	1	Y or N		APO	
Intraoperative Management	Intraoperative Management	BloodProductType2		Text	20		yes	APO	
Intraoperative Management	Intraoperative Management	BloodProductVolume2		Text	20			APO	
Intraoperative Management	Intraoperative Management	Drug2		Text	20			APO	
Intraoperative Management	Intraoperative Management	Drug2Time		Text	20			APO	
Intraoperative Management	Intraoperative Management	Drug2Dose		Text	20			APO	
Intraoperative Management	Intraoperative Management	Drug3		Text	20			APO	
Intraoperative Management	Intraoperative Management	Drug3Time		Text	20			APO	
Intraoperative Management	Intraoperative Management	Drug3Dose		Text	20			APO	
Intraoperative Management	Intraoperative Management	Drug4		Text	20			APO	
Intraoperative Management	Intraoperative Management	Drug4Time		Text	20			APO	
Intraoperative Management	Intraoperative Management	Drug4Dose		Text	20			APO	

OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Intraoperative Management	Intraoperative Management	Drugs5		Text	20			AOPO	
Intraoperative Management	Intraoperative Management	Drugs5Time		Text	20			AOPO	
Intraoperative Management	Intraoperative Management	Drugs5Doseage		Text	20			AOPO	
Intraoperative Management	Intraoperative Management	Crystalloids		Text	1	Y or N		AOPO	
Intraoperative Management	Intraoperative Management	CrystalloidsType		Text	20			AOPO	
Intraoperative Management	Intraoperative Management	CrystalloidsVolume		Text	20			AOPO	
Intraoperative Management	Intraoperative Management	HR1ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	HR2ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	HR3ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	HR4ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	HL1ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	HL2ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	HL3ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	HL4ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	RLU1ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	RLU2ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	RLU3ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	RLU4ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	LLU1ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	LLU2ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	LLU3ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	LLU4ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	LI1ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	LI2ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	LI3ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	LI4ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	KI1ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	KI2ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	KI3ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	KI4ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	PA1ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	PA2ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	PA3ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	PA4ORTeam		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	AnesthesiaORTeam1		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	AnesthesiaORTeam2		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	AnesthesiaORTeam3		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	CirculatorORTeam1		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	CirculatorORTeam2		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	CirculatorORTeam3		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	ScrubORTeam1		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	ScrubORTeam2		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	ScrubORTeam3		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	Other1TeamName		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	Other1ORTeam1		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	Other1ORTeam2		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	Other1ORTeam3		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	Other1ORTeam4		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	Other2TeamName		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	Other2ORTeam1		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	Other2ORTeam2		Text	25			AOPO	
Intraoperative Management	Intraoperative Management	Other2ORTeam3		Text	25			AOPO	

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Kidney Data	Kidney Data	KIClampDate/Time		Date/Time	8			AOPO	
Kidney Data	Kidney Data	WarmischemicTime		Text	15	Y or N		AOPO	
Kidney Data	Kidney Data	WITDuration		Text	15	Null unless WIT is Yes		AOPO	
Kidney Data	Kidney Data	InstuFlush		Text	5	Y or N		AOPO	
Kidney Data	Kidney Data	KIFlushSolution		Text	25			AOPO	
Kidney Data	Kidney Data	KIFlushVolume		Text	15			AOPO	
Kidney Data	Kidney Data	KIFlushChar		Text	2	1, 2, 3 or 4		AOPO	
Kidney Data	Kidney Data	KISolutionSolution		Text	25			AOPO	
Kidney Data	Kidney Data	EnBloc		Text	5	Y or N		AOPO	
Kidney Data	Kidney Data	TypeNode		Text	1	Y or N		AOPO	
Kidney Data	Kidney Data	TypeSpleen		Text	1	Y or N		AOPO	
Kidney Data	Kidney Data	TypeBloodClot		Text	1	Y or N		AOPO	
Kidney Data	Kidney Data	TypeCellPrep		Text	1	Y or N		AOPO	
Kidney Data	Kidney Data	TypeCell		Text	1	Y or N		AOPO	
Kidney Data	Kidney Data	TypeCell		Text	1	Y or N		AOPO	
Kidney Data	Kidney Data	Nephrectomy/Surgeon		Text	50			AOPO	
Kidney Data	Kidney Data	AssistantSurgeon		Text	50			AOPO	
Kidney Data	Kidney Data	BacktableFlush		Text	5	Y or N		AOPO	
Kidney Data	Kidney Data	BacktableFlushVolume		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIRecoverType		Text	20	Transplanted, Research,			
Kidney Data	Left Kidney Anatomy	LKIKidneyLength		Text	10	Discarded and Not Recovered		AOPO	
Kidney Data	Left Kidney Anatomy	LKIKidneyWidth		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIArteriesNumber		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIArteriesLength1		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIArteriesLength2		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIArteriesLength3		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIArteriesDiameter1		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIArteriesDiameter2		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIArteriesDiameter3		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIArteriesDistanceApart		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIAorticClut		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIVeinsNumber		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIVeinsLength1		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIVeinsLength2		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIVeinsLength3		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIVeinsDiameter1		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIVeinsDiameter2		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIVeinsDiameter3		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIVeinsDistanceApart		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIFullVenaCava		Text	1	Y or N		AOPO	
Kidney Data	Left Kidney Anatomy	LKIUreters		Text	10	Single or Double		AOPO	
Kidney Data	Left Kidney Anatomy	LKIUretersLength1		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIUretersLength2		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIUretersLength3		Text	10			AOPO	
Kidney Data	Left Kidney Anatomy	LKIBloodResults		Text	250			AOPO	
Kidney Data	Left Kidney Anatomy	LKIBloodPlaque		Text	50			AOPO	
Kidney Data	Left Kidney Anatomy	LKIArterialPlaque		Text	5			AOPO	
Kidney Data	Left Kidney Anatomy	LKIArterialArea		Text	5			AOPO	
Kidney Data	Left Kidney Anatomy	LKICapsuleTear		Text	5			AOPO	

OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Kidney Data	Left Kidney Anatomy	Left Kidney Anatomy		Text	5			AOPO	
Kidney Data	Left Kidney Anatomy	LKISubcapsularHematoma		Text	5			AOPO	
Kidney Data	Left Kidney Anatomy	LKICysts/Discoloration		Text	5			AOPO	
Kidney Data	Left Kidney Anatomy	LKIBiopsy		Text	5			AOPO	
Kidney Data	Left Kidney Anatomy	LKIAbnormalities		Text	1	Y or N		AOPO	
Kidney Data	Left Kidney Anatomy	LKISurgicalDamage		Text	1	Y or N		AOPO	
Kidney Data	Left Kidney Anatomy	LKIDiagramLink		Picture	0			AOPO	
Kidney Data	Left Kidney Anatomy	LKIMultAteriesCuff		Text	1	Y or N		AOPO	
Kidney Data	Right Kidney Anatomy	RKIRecoverType		Text	20	Transplanted, Research, Discarded and Not Recovered		AOPO	
Kidney Data	Right Kidney Anatomy	RKIKidneyLength		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIKidneyWidth		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAteriesNumber		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAteriesLength1		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAteriesLength2		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAteriesLength3		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAteriesDiameter1		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAteriesDiameter2		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAteriesDiameter3		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAteriesDistanceApart		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAorticCuff		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIVeinsNumber		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIVeinsLength1		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIVeinsLength2		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIVeinsLength3		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIVeinsDiameter1		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIVeinsDiameter2		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIVeinsDiameter3		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIFulthVenaCava		Text	1	Y or N		AOPO	
Kidney Data	Right Kidney Anatomy	RKIUreters		Text	10	Single or Double		AOPO	
Kidney Data	Right Kidney Anatomy	RKIUretersLength1		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIUretersLength2		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIUretersLength3		Text	10			AOPO	
Kidney Data	Right Kidney Anatomy	RKIComments		Text	250			AOPO	
Kidney Data	Right Kidney Anatomy	RKIBiopsyResults		Text	50			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAorticPlaque		Text	5			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAterialPlaque		Text	5			AOPO	
Kidney Data	Right Kidney Anatomy	RKInfarctedArea		Text	5			AOPO	
Kidney Data	Right Kidney Anatomy	RKICapsuleTear		Text	5			AOPO	
Kidney Data	Right Kidney Anatomy	RKISubcapsularHematoma		Text	5			AOPO	
Kidney Data	Right Kidney Anatomy	RKICysts/Discoloration		Text	5			AOPO	
Kidney Data	Right Kidney Anatomy	RKIBiopsy		Text	5			AOPO	
Kidney Data	Right Kidney Anatomy	RKIAbnormalities		Text	1	Y or N		AOPO	
Kidney Data	Right Kidney Anatomy	RKISurgicalDamage		Text	1	Y or N		AOPO	
Kidney Data	Right Kidney Anatomy	RKIDiagramLink		Picture	0			AOPO	
Kidney Data	Right Kidney Anatomy	RKIMultAteriesCuff		Text	1	Y or N		AOPO	
Heart Data	Heart Data	HRRecoveryType		Text	15	Transplanted, Valves, Research, Discarded or Not Recovered		AOPO	
Heart Data	Heart Data	HRFlushSolution		Text	50			AOPO	
Heart Data	Heart Data	HRFlushVolume		Text	50			AOPO	
Heart Data	Heart Data	HRStorageSolution		Text	50			AOPO	

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OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Tissue Data	Tissue Data	EyeTissueBank		Text	30			AOPO	
Tissue Data	Tissue Data	SkinRecovered		Text	50	Y or N		AOPO	
Tissue Data	Tissue Data	SkinNoExplanation		Text	50	Null unless recovered = No		AOPO	
Tissue Data	Tissue Data	SkinTechnician		Text	30			AOPO	
Tissue Data	Tissue Data	SkinTissueBank		Text	30			AOPO	
Tissue Data	Tissue Data	Bone/TendonRecovered		Text	5			AOPO	
Tissue Data	Tissue Data	B/TNoExplanation		Text	50	Null unless recovered = No		AOPO	
Tissue Data	Tissue Data	B/TTechnician		Text	30			AOPO	
Tissue Data	Tissue Data	B/TTissueBank		Text	30			AOPO	
Tissue Data	Tissue Data	SaphenousVeinRecovered		Text	5	Y or N		AOPO	
Tissue Data	Tissue Data	SaphenousVeinNumber		Text	5			AOPO	
Tissue Data	Tissue Data	SVNoExplanation		Text	50	Null unless recovered = No		AOPO	
Tissue Data	Tissue Data	SVTechnician		Text	30			AOPO	
Tissue Data	Tissue Data	SVTissueBank		Text	30			AOPO	
Tissue Data	Tissue Data	HeartValveRecovered		Text	5	Y or N		AOPO	
Tissue Data	Tissue Data	HVNoExplanation		Text	50	Null unless recovered = No		AOPO	
Tissue Data	Tissue Data	HVTTechnician		Text	30			AOPO	
Tissue Data	Tissue Data	HVTTissueBank		Text	30			AOPO	
Tissue Data	Tissue Data	TDDataOtherName		Text	20			AOPO	
Tissue Data	Tissue Data	TDOtherRecovered		Text	5	Y or N		AOPO	
Tissue Data	Tissue Data	TDOtherNoExplanation		Text	50			AOPO	
Tissue Data	Tissue Data	TDOtherTechnician		Text	30			AOPO	
Tissue Data	Tissue Data	TDOtherTissueBank		Text	30			AOPO	
General Notes	General Notes	CaseComments		Text	n	Y or reason for No. If no, user must select from list and reason then becomes the data for this field			
Organ Recovery	Organ Recovery Information	OrgansSuitable	.donr suitable	Text	5		ORSB	CDR	
Organ Recovery	Organ Recovery Information	OrgansSuitableOther	.donr unsuitable	Text	30	Is null unless suitable (unsuitable reason) code = other		CDR	
Organ Recovery	Organ Recovery Information	NonHeartBeatDonor	.donr2 nonhrt	Text	1	Valid entries are Y or N		CDR	
Organ Recovery	Organ Recovery Information	CoreCookingUsed	.donr2 corecool	Text	1	Valid entries are Y or N. Null unless nonheartbeat is Y		CDR	
Organ Recovery	Organ Recovery Information	EstWarmIschemicTime	.donr2 warmtime	Text	3	Valid range is 0 to 120 minutes.		CDR	
Organ Recovery	Organ Recovery Information	ClampDataTime	.donr2 clampdt	Date		Null unless nonheartbeat is Y. Must be valid date. Must be less than or equal to one day of recovery date.		CDR	
Organ Recovery	Organ Recovery Information	TimeZone	.donr2 timezn	Text	3	Valid codes only	TMZN	CDR	
Organ Recovery	Organ Recovery Information	LeftKidRecovered	.donr2 klracd	Text	1	Y or N		CDR	
Organ Recovery	Organ Recovery Information	RightKidRecovered	.donr2 krracd	Text	1	Y or N		CDR	
Organ Recovery	Organ Recovery Information	LiverRecovered	.donr2 lracd	Text	1	Y or N		CDR	
Organ Recovery	Organ Recovery Information	IntestineRecovered	.donr2 inacd	Text	1	Y or N		CDR	
Organ Recovery	Organ Recovery Information	PancreasRecovered	.donr2 paracd	Text	1	Y or N		CDR	
Organ Recovery	Organ Recovery Information	HeartRecovered	.donr2 hmracd	Text	1	Y or N		CDR	
Organ Recovery	Organ Recovery Information	LeftLungRecovered	.donr2 lllracd	Text	1	Y or N		CDR	
Organ Recovery	Organ Recovery Information	RightLungRecovered	.donr2 rllracd	Text	1	Y or N		CDR	
Organ Recovery	Organ Recovery Information	LKNoRecvReason		Text	3	Valid codes only	RCVR	CDR	
Organ Recovery	Organ Recovery Information	LNNoRecvReason		Text	3	Valid codes only	RCVR	CDR	
Organ Recovery	Organ Recovery Information	LNNoRecvReason		Text	3	Valid codes only	RCVR	CDR	Different number for each organ

OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Organ Recovery	Organ Recovery Information	INNotRecvReason		Text		3 Valid codes only	RCVR	CDR	
Organ Recovery	Organ Recovery Information	PANotRecvReason		Text		3 Valid codes only	RCVR	CDR	
Organ Recovery	Organ Recovery Information	HRNotRecvReason		Text		3 Valid codes only	RCVR	CDR	
Organ Recovery	Organ Recovery Information	LLNotRecvReason		Text		3 Valid codes only	RCVR	CDR	
Organ Recovery	Organ Recovery Information	RLNotRecvReason		Text		3 Valid codes only	RCVR	CDR	
Organ Recovery	Organ Recovery Information	LKIRecvTeamProviderNum	.donorg cvpvr	Text		7 Y or N	PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	RIIRecvTeamProviderNum		Text		7 Y or N	PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	LIIRecvTeamProviderNum		Text		7 Y or N	PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	INIRecvTeamProviderNum		Text		7 Y or N	PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	PAIRecvTeamProviderNum		Text		7 Y or N	PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	HRIRecvTeamProviderNum		Text		7 Y or N	PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	LLIRecvTeamProviderNum		Text		7 Y or N	PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	RLIRecvTeamProviderNum		Text		7 Y or N	PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	FLUSolution	.donorg flush	Text		5 Valid codes only	FLSN	CDR	
Organ Recovery	Organ Recovery Information	StorageSolution	.donorg storage	Text		5 Valid codes only	STOR	CDR	
Organ Recovery	Organ Recovery Information	Pump	.donorg pump	Text		3 Valid entries are Y or N	CDR	CDR	
Organ Recovery	Organ Recovery Information	PlacedBy	.donorg plby	Text		5 Valid codes only	PLBY	CDR	
Organ Recovery	Organ Recovery Information	ShareType	.donorg share	Text		5 Valid codes only	ORSH	CDR	
Organ Recovery	Organ Recovery Information	DispositionCode	.donorg dsp	Text		5 Valid codes only	DSPN	CDR	
Organ Recovery	Organ Recovery Information	DiscardReason	.donorg dsp	Text		Valid codes only - Null unless disposition code = discard. Recovery team number must be filled in in this case.	DCRD	CDR	
Organ Recovery	Organ Recovery Information	RecipientFirstName	.rtr ftr name	Text	5	5	CDR	CDR	
Organ Recovery	Organ Recovery Information	RecipientLastName	.rtr ltr name	Text	5	5	CDR	CDR	
Organ Recovery	Organ Recovery Information	RecipientCenterProvNum	.prvdr prnum	Text	5	5 Valid codes only	PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	RIIPushSolution		Text	5	5 Valid codes only	FLSN	CDR	
Organ Recovery	Organ Recovery Information	RIISolution		Text	5	5 Valid codes only	STOR	CDR	
Organ Recovery	Organ Recovery Information	RIIPump		Text	3	3 Valid entries are Y or N	CDR	CDR	
Organ Recovery	Organ Recovery Information	RIIPacedBy		Text	5	5 Valid codes only	PLBY	CDR	
Organ Recovery	Organ Recovery Information	RIIShareType		Text	5	5 Valid codes only	ORSH	CDR	
Organ Recovery	Organ Recovery Information	RIIDispositionCode		Text	5	5 Valid codes only	DSPN	CDR	
Organ Recovery	Organ Recovery Information	DiscardReason		Text		Valid codes only - Null unless disposition code = discard. Recovery team number must be filled in in this case.	DCRD	CDR	
Organ Recovery	Organ Recovery Information	RecipientFirstName		Text	5	5	CDR	CDR	
Organ Recovery	Organ Recovery Information	RecipientLastName		Text	5	5	CDR	CDR	
Organ Recovery	Organ Recovery Information	RecipientCenterProvNum		Text	5	5 Valid codes only	PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	LIIPushSolution		Text	5	5 Valid codes only	FLSN	CDR	
Organ Recovery	Organ Recovery Information	LIISolution		Text	5	5 Valid codes only	STOR	CDR	
Organ Recovery	Organ Recovery Information	LIIPump		Text	3	3 Valid entries are Y or N	CDR	CDR	
Organ Recovery	Organ Recovery Information	LIIPacedBy		Text	5	5 Valid codes only	PLBY	CDR	
Organ Recovery	Organ Recovery Information	LIIShareType		Text	5	5 Valid codes only	ORSH	CDR	
Organ Recovery	Organ Recovery Information	LIIDispositionCode		Text	5	5 Valid codes only	DSPN	CDR	
Organ Recovery	Organ Recovery Information	DiscardReason		Text		Valid codes only - Null unless disposition code = discard. Recovery team number must be filled in in this case.	DCRD	CDR	
Organ Recovery	Organ Recovery Information	RecipientFirstName		Text	5	5	CDR	CDR	
Organ Recovery	Organ Recovery Information	RecipientLastName		Text	5	5	CDR	CDR	
Organ Recovery	Organ Recovery Information	RecipientCenterProvNum		Text	5	5 Valid codes only	PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	LIIPushSolution		Text	5	5 Valid codes only	FLSN	CDR	
Organ Recovery	Organ Recovery Information	LIISolution		Text	5	5 Valid codes only	STOR	CDR	
Organ Recovery	Organ Recovery Information	LIIPump		Text	3	3 Valid entries are Y or N	CDR	CDR	
Organ Recovery	Organ Recovery Information	LIIPacedBy		Text	5	5 Valid codes only	PLBY	CDR	
Organ Recovery	Organ Recovery Information	LIIShareType		Text	5	5 Valid codes only	ORSH	CDR	
Organ Recovery	Organ Recovery Information	LIIDispositionCode		Text	5	5 Valid codes only	DSPN	CDR	
Organ Recovery	Organ Recovery Information	DiscardReason		Text		Valid codes only - Null unless disposition code = discard. Recovery team number must be filled in in this case.	DCRD	CDR	
Organ Recovery	Organ Recovery Information	RecipientFirstName		Text	5	5	CDR	CDR	
Organ Recovery	Organ Recovery Information	RecipientLastName		Text	5	5	CDR	CDR	
Organ Recovery	Organ Recovery Information	RecipientCenterProvNum		Text	5	5 Valid codes only	PRVDRS	CDR	

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OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Organ Recovery	Organ Recovery Information	LLUFushSolution		Text	5	Valid codes only	FLSN	CDR	
Organ Recovery	Organ Recovery Information	LLUStorageSolution		Text	5	Valid codes only	STOR	CDR	
Organ Recovery	Organ Recovery Information	LLUPump		Text	3	Valid codes only		CDR	
Organ Recovery	Organ Recovery Information	LLUPlaceBy		Text	5	Valid codes only	PLBY	CDR	
Organ Recovery	Organ Recovery Information	LLUShare Type		Text	5	Valid codes only	ORSH	CDR	
Organ Recovery	Organ Recovery Information	LLUDispositionCode		Text	5	Valid codes only	DSPN	CDR	
Organ Recovery	Organ Recovery Information	LLUDiscardReason		Text	5	Valid codes only - Null unless disposition code = discard.			
Organ Recovery	Organ Recovery Information	LLURecipientFirst Name		Text	5	Recovery team number must be filled in in this case.	DCPD	CDR	
Organ Recovery	Organ Recovery Information	LLURecipientLast Name		Text	5			CDR	
Organ Recovery	Organ Recovery Information	LLURecipientCenterProxNum		Text	5		PRVDRS	CDR	
Organ Recovery	Organ Recovery Information	RLUFushSolution		Text	5	Valid codes only	FLSN	CDR	
Organ Recovery	Organ Recovery Information	RLUStorageSolution		Text	5	Valid codes only	STOR	CDR	
Organ Recovery	Organ Recovery Information	RLUPump		Text	3	Valid codes only		CDR	
Organ Recovery	Organ Recovery Information	RLUPlaceBy		Text	5	Valid codes only	PLBY	CDR	
Organ Recovery	Organ Recovery Information	RLUShare Type		Text	5	Valid codes only	ORSH	CDR	
Organ Recovery	Organ Recovery Information	RLUDispositionCode		Text	5	Valid codes only	DSPN	CDR	
Organ Recovery	Organ Recovery Information	RLUDiscardReason		Text		Valid codes only - Null unless disposition code = discard.			
Organ Recovery	Organ Recovery Information	RLURecipientFirst Name		Text	5	Recovery team number must be filled in in this case.	DCPD	CDR	
Organ Recovery	Organ Recovery Information	RLURecipientLast Name		Text	5			CDR	
Organ Recovery	Organ Recovery Information	RLURecipientCenterProxNum		Text	5		PRVDRS	CDR	
Match Run Input	Match Run Specific	DonorCenterCode	DCENTER	Text	4			MR	
Match Run Input	Match Run Specific	UserID	USERID	Text	2			MR	
Match Run Input	Match Run Specific	OrgansToRun	ORG1	Text	2	AL,HR,HL,KILLIU,PA,KP,IN,PI		MR	
Match Run Input	Match Run Specific	OrgansToRun	ORG2	Text	2	AL,HR,HL,KILLIU,PA,KP,IN,PI		MR	
Match Run Input	Match Run Specific	OrgansToRun	ORG3	Text	2	AL,HR,HL,KILLIU,PA,KP,IN,PI		MR	
Match Run Input	Match Run Specific	OrgansToRun	ORG4	Text	2	AL,HR,HL,KILLIU,PA,KP,IN,PI		MR	
Match Run Input	Match Run Specific	OrgansToRun	ORG5	Text	2	AL,HR,HL,KILLIU,PA,KP,IN,PI		MR	
Match Run Input	Match Run Specific	OrgansToRun	ORG6	Text	2	AL,HR,HL,KILLIU,PA,KP,IN,PI		MR	
Match Run Input	Match Run Specific	OrgansToRun	ORG7	Text	2	AL,HR,HL,KILLIU,PA,KP,IN,PI		MR	
Match Run Input	Match Run Specific	OrgansToRun	ORG8	Text	2	AL,HR,HL,KILLIU,PA,KP,IN,PI		MR	
Match Run Input	Match Run Specific	KidneySideCode	KSIDE	Text	1	L,R,B		MR	
Match Run Input	Match Run Specific	CrossMatch	XMATCH	Text	1	Y or N		MR	
Match Run Input	Match Run Specific	LeftBronchus	LBRONCHUS	Text	2			MR	
Match Run Input	Match Run Specific	RightBronchus	RBRONCHUS	Text	2			MR	
Match Run Input	Match Run Specific	TransverseChest	TRCHEST	Text	2			MR	
Match Run Input	Match Run Specific	VerticalChest	VTCHES	Text	2			MR	
Match Run Input	Match Run Specific	DonorHospZip	DZIP	Text	5			MR	

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OIS Database Elements

Form Name	Functional Area	Notes Field Name	OTIS Name	Field Type	Field Length	Validation Rule(s)	OTIS Look-up Table	Form Origin	Comments
Match Run Input	Match Run Specific	LocalVariances	DLOCAL	Text		9 L1=7, RUN=2, SEOPF=1		MR	
Match Run Input	Match Run Specific	Tray	TRAY	Text	1			MR	
Match Run Input	Match Run Specific	PrevGastroIntestine	PVGASTRO	Text	1	Y or N		MR	
Match Run Input	Match Run Specific	HCVPos	HCV	Text				MR	

Appendix

Lookup Lists

Lookup Table Names

List Name	OTIS Table Name
ABO	ABO
AHLA	AHLA
ApproachedBy	APRC
BHLA	BHLA
BloodProducts	
CancerSite	CNLOC
CaseType	CDTYP
CauseofDeath	DTHC
CellValue	
CircumstancesofDeath	DTHCM
DiscardReasonCode	DCRD
DispositionCode	DSPN
DRHLA	DRHLA
DurationCode	DURTN
FlushSolution	FLSN
HighGradeSEOPF	
MechanismofDeath	DTHM
Medications	
NYCellValue	
OrganConsentReason	OCNS
OrgansSuitable	ORSB
OrganType	
PlacedBy	PLBY
Race	RACE
RecoveryReasonCode	RCVR
ReferralType	
Region6	
Relationship	RLTYP
SEOPF	
Serology	SRLG
ShareType	ORSH
State	STATE
StorageSolution	STOR
TimeZone	TMZN

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Consent Information	ApproachedBy	1	Family Initiated	APRC
Consent Information	ApproachedBy	2	Physician	APRC
Consent Information	ApproachedBy	3	Nurse	APRC
Consent Information	ApproachedBy	4	Clergy	APRC
Consent Information	ApproachedBy	5	OPO Coordinator	APRC
Consent Information	ApproachedBy	6	Social Worker	APRC
Consent Information	ApproachedBy	999	Other	APRC
Consent Information	OrgansSuitable	1	HIV+	ORSB
Consent Information	OrgansSuitable	2	HCV+	ORSB
Consent Information	OrgansSuitable	3	Hepatitis B+	ORSB
Consent Information	OrgansSuitable	4	Brain Death Criteria Not Met	ORSB
Consent Information	OrgansSuitable	5	Medical History	ORSB
Consent Information	OrgansSuitable	6	Social History	ORSB
Consent Information	OrgansSuitable	7	Cancer	ORSB
Consent Information	OrgansSuitable	8	Age	ORSB
Consent Information	OrgansSuitable	999	Other, Specify	ORSB
Donor Information	CircumstancesofDeath	1	Motor Vehicle Accident	DTHCM
Donor Information	CircumstancesofDeath	2	Suicide	DTHCM
Donor Information	CircumstancesofDeath	3	Homicide	DTHCM
Donor Information	CircumstancesofDeath	4	Child-Abuse	DTHCM
Donor Information	CircumstancesofDeath	5	Non-Motor Vehicle Accident	DTHCM
Donor Information	CircumstancesofDeath	997	None	DTHCM
Donor Information	CircumstancesofDeath	998	Unknown	DTHCM
Donor Information	CircumstancesofDeath	999	Other	DTHCM
Donor Information	MechanismofDeath	1	Drowning	DTHM
Donor Information	MechanismofDeath	2	Seizure	DTHM
Donor Information	MechanismofDeath	3	Drug Intoxication	DTHM
Donor Information	MechanismofDeath	4	Asphyxiation	DTHM
Donor Information	MechanismofDeath	5	Cardiovascular	DTHM
Donor Information	MechanismofDeath	6	Electrical	DTHM
Donor Information	MechanismofDeath	7	Gunshot Wound	DTHM
Donor Information	MechanismofDeath	8	Stab	DTHM
Donor Information	MechanismofDeath	9	Blunt Injury	DTHM
Donor Information	MechanismofDeath	10	Sids	DTHM
Donor Information	MechanismofDeath	11	Intracranial Hemorrhage/Stroke	DTHM

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Donor Information	MechanismofDeath	995	Gunshot/Stab Undetermined	DTHM
Donor Information	MechanismofDeath	997	None	DTHM
Donor Information	MechanismofDeath	998	Unknown	DTHM
Donor Information	MechanismofDeath	999	Other	DTHM
Donor Information	CauseofDeath	1	Anoxia	DTHC
Donor Information	CauseofDeath	2	Cerebrovascular/Stroke	DTHC
Donor Information	CauseofDeath	3	Head Trauma	DTHC
Donor Information	CauseofDeath	4	Cns Tumor	DTHC
Donor Information	CauseofDeath	998	Unknown	DTHC
Donor Information	CauseofDeath	999	Other	DTHC
Donor Information	Race	1	White	RACE
Donor Information	Race	2	Black	RACE
Donor Information	Race	3	American Indian/Alaskan Native	RACE
Donor Information	Race	4	Asian	RACE
Donor Information	Race	5	Pacific Islander	RACE
Donor Information	Race	6	Mid-East/Arabian	RACE
Donor Information	Race	7	Indian Sub-Continent	RACE
Donor Information	Race	8	Undetermined Asian/Pacific Islander	RACE
Donor Information	Race	998	Unknown	RACE
Donor Information	Race	999	Other	RACE
Case Information	CaseType	1	Referral Only	CDTYP
Case Information	CaseType	2	Consented But Not Recovered	CDTYP
Case Information	CaseType	3	Recovered	CDTYP
Case Information	ReferralType		Organ Referral Only	
Case Information	ReferralType		Tissue Referral Only	
Case Information	ReferralType		Organ & Tissue Referral	
Donor Information	ABO	1	O	ABO
Donor Information	ABO	2	A	ABO
Donor Information	ABO	3	B	ABO
Donor Information	ABO	4	AB	ABO
Donor Information	ABO	5	A1	ABO
Donor Information	ABO	6	A2	ABO
Donor Information	ABO	7	A1B	ABO
Donor Information	ABO	8	A2B	ABO
Donor Information	ABO	998	Unknown	ABO

Center Data File

Center Data File

ALBP	3	205-783-3000	N	4	0	0	0	6-MAY-86	
ALOB	3	800-252-3677	Y	3	4	13	33	7-APR-86 2-SEP-89	-26
ALUA	3	800-252-3677	Y	3	0	0	12	7-APR-86 21-JAN-91	-26
ARBH	3	501-224-2623	N		0	0	0	21-FEB-89 13-OCT-89	
ARCH	3	501-224-2623	N		0	1	0	5-FEB-87 13-OCT-89	
AROR	3	501-224-2623	N		0	0	0	2-MAR-89 6-JUL-89	
ARUA	3	501-224-2623	N	4	5	1	1	7-APR-86 13-OCT-89	
ARUC	3	501-661-5000	N	4	0	0	0	7-APR-86	
AZGC	5	602-251-2882	N		0	0	0	14-MAR-90	
AZGS	5	602-251-2882	N	4	41	32	26	7-APR-86 5-FEB-88	
AZHH	5	602-251-2882	N		0	0	0	7-JUL-88	
AZOB	5	602-251-2882	N		0	0	0	3-OCT-88	
AZPH	5	602-251-2882	N	4	0	0	0	22-JUL-86	
AZSJ	5	602-251-2882	N		0	0	0	7-JUL-88	
AZTV	5	602-251-2882	N	4	0	0	0	7-APR-86 12-NOV-87	
AZUA	5	602-251-2882	N		0	0	0	27-APR-87 27-APR-87	
CABE	5	310-825-7651	N		0	0	0	4-APR-90 5-AUG-92	
CABH	5	415-540-4493	N		0	0	0	8-FEB-88 29-JUL-88	
CACL	5	310-825-7651	N		0	0	0	4-APR-90 5-AUG-92	
CACS	5	310-825-7651	N		0	0	0	3-AUG-89 15-APR-92	
CADN	5	800-553-6667	N		0	0	0	30-JUL-88	
CAEM	5	310-825-7651	N		0	0	0	6-MAR-92 22-MAR-90	
CAGH	5	619-455-9100	N		0	0	0	13-JUL-90	
CAGS	5	916-457-7672	N		0	0	0	18-MAY-89 27-MAR-92	
CAIM	5	310-825-7651	N		0	0	0	22-MAR-90 5-AUG-92	
CALA	5	310-825-7651	N		0	0	0	4-APR-90 5-AUG-92	
CALB	5	310-825-7651	N		0	0	0	4-APR-90 5-AUG-92	
CALL	5	310-825-7651	N	4	0	0	0	7-APR-86 5-AUG-92	
CAMH	5	707-525-5297	N		0	0	0	13-OCT-87	
CAOP	5	800-338-6112	N		0	0	0	20-JAN-88 5-DEC-91	
CAOT	5	619-294-6263	N		0	0	0	7-JUL-89	
CAPM	5	415-563-4321	N	4	0	1	3	7-APR-86 16-AUG-89	
CARZ	5	213-413-6219	N		0	0	0	25-JAN-90	
CASB	5	310-825-7651	N		0	0	0	4-APR-90 5-AUG-92	
CASC	5	213-825-7651	N		0	0	0	4-APR-90	
CASD	5	619-294-6257	N	4	0	2	5	7-APR-86 26-NOV-88	
CASF	5	415-476-1551	N	4	0	32	23	7-APR-86 2-JAN-90	
CASG	5	916-457-7672	N		0	0	0	18-MAY-89 27-MAR-92	
CASH	5	619-541-3400	N	4	0	0	0	12-FEB-92	
CASJ	5	310-825-7651	N		0	0	0	4-APR-90 5-AUG-92	
CASM	5	916-457-7672	N	4	0	0	0	7-APR-86 27-MAR-92	
CASU	5	415-723-6661	N		0	0	0	19-FEB-88 10-MAY-88	
CASV	5	213-483-6830	N	4	0	21	29	7-APR-86 4-AUG-90	
CAUC	5	310-825-7651	N		0	0	0	25-MAY-89 5-AUG-92	
CAUH	5	213-483-6830	N	0	0	0	0	23-AUG-91	
CAWM	5	310-825-7651	N		0	0	0	4-APR-90 5-AUG-92	
CNHF	99	902-453-2640	N		0	0	0	5-DEC-86	
CNUA	99	403-432-6022	N		0	0	0	5-DEC-86	
CNVG	99	604-875-4111	N		0	0	0	5-DEC-86	
CNWM	7	317-712-6380	N		0	0	0	5-DEC-86	
COCH	8	303-830-1141	N		0	0	0	25-APR-90 25-APR-90	
COIA	8	303-321-6027	N		0	0	0	20-DEC-90	

COMH	8	800-448-4644	Y		0	0	0	27-NOV-91	
COPM	8	800-448-4644	Y		0	0	0	19-JAN-90	10
CORS	8	800-448-4644	Y	3	9	0	0	29-MAR-88 4-MAY-90	8
COSL	8	800-448-4644	Y	3	34	11	27	7-APR-86 4-MAY-90	-4
COUC	8	800-448-4644	Y	4	1	0	0	7-APR-86 19-JAN-90	10
CTHH	1	203-524-2256	N	4	0	2	1	7-APR-86 10-DEC-88	
CTYN	1	800-446-6362	N	4	0	0	0	7-APR-86	
DCCH	2	202-223-8229	N	4	0	4	1	7-APR-86 17-NOV-89	
DCGU	2	202-223-8229	N	4	18	21	42	7-APR-86 26-JAN-89	
DCGW	2	202-223-8229	N	4	5	4	15	7-APR-86 14-DEC-88	
DCHU	2	202-223-8229	N	3	3	1	7	7-APR-86 14-DEC-88	
DCTC	2	202-223-8229	N		0	1	0	10-FEB-88 26-SEP-88	
DCWH	2	202-223-8229	N	3	17	28	38	7-APR-86 14-DEC-88	
DCWR	2	202-223-8229	N	3	0	13	21	7-APR-86 28-OCT-88	
DEAI	2	302-651-4426	N	0	0	0	0	9-SEP-91	
DIAG	1	1/1/01	N	4	0	0	0	7-APR-86	
FLAC	3	813-253-2640	Y		0	0	0	15-JAN-91	0
FLBG	3	305-463-3131	N	3	0	0	0	7-APR-86	
FLDB	3	305-896-6611	N	3	0	0	0	7-APR-86	
FLFH	3	407-849-5912	Y	1	91	24	32	7-APR-86 6-AUG-90	70
FLFL	3	904-395-0254	Y	1	0	0	0	25-AUG-89 27-APR-92	20
FLFM	3	305-896-6611	N	3	0	0	0	7-APR-86	
FLFR	3	813-939-1147	Y		0	0	0	10-APR-91	0
FLJM	3	800-255-4483	Y	1	120	-12	16	7-APR-86 3-DEC-89	199
FLJT	3	904-366-7900	Y		0	0	0	29-MAR-89	21
FLMP	3	800-255-4483	Y		0	0	0	10-APR-92 3-DEC-89	
FLMV	3	305-325-7320	N	3	0	0	0	7-APR-86	
FLOM	3	305-896-6611	N	3	0	0	0	7-APR-86	
FLSF	3	813-253-2640	Y	1	137	99	94	7-APR-86 20-DEC-89	191
FLSW	3	813-939-1147	Y		0	0	0	10-APR-91	8
FLTG	3	813-253-2640	Y	1	0	0	0	7-APR-86 15-JAN-91	-83
FLTO	3	904-887-7886	N	4	1	0	0	7-APR-86 28-JAN-87	
FLTV	3	813-253-0711	N	3	0	0	0	7-APR-86	
FLUF	3	800-535-4483	Y	1	136	73	96	7-APR-86 31-JAN-90	14
GAEH	3	800-544-6667	Y	2	0	0	0	7-APR-86 21-DEC-89	4
GAEM	3	800-544-6667	Y	3	0	7	1	7-APR-86 13-JUN-89	-5
GAEU	3	800-544-6667	N	3	0	0	16	20-SEP-88	
GAEX	3	404-321-4566	N	3	0	0	0	7-APR-86	
GAGM	3	404-321-4566	N	2	0	0	0	7-APR-86 30-SEP-86	
GALL	3	800-544-6667	Y		0	0	0	10-FEB-88	0
GAMC	3	706-721-3893	Y	1	61	38	61	7-APR-86 18-DEC-89	79
GAPH	3	800-544-6667	Y		0	0	0	9-AUG-88 9-AUG-88	-5
GASJ	3	800-544-6667	N		0	0	0	14-OCT-87 21-JUN-88	
GAUH	3	404-721-3893	N	4	0	0	0	27-JUN-88	
HIOP	5	808-599-7630	N		0	0	0	19-AUG-92	
HISF	5	808-599-7630	N		0	0	0	29-APR-87	
HOPE	99	519-663-3000	N		0	0	0	5-DEC-86	
IAIM	8	515-283-5744	N		0	1	0	24-NOV-87 17-SEP-88	
IAIV	8	319-356-7426	N	4	0	13	0	7-APR-86 13-DEC-89	
IAMH	8	515-247-4261	N	4	0	0	0	2-JUL-87	
IAOP	8	319-356-7426	N		0	0	0	25-SEP-89	
ILCM	7	312-880-3330	N	4	2	0	0	7-APR-86 21-AUG-89	

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ILCR	7	312-543-6397	N	4	0	5	1	7-APR-8610-OCT-88	
ILED	7	312-649-3338	N	4	0	0	0	7-APR-86	
ILEH	7	312-492-2000	N		0	0	0	18-DEC-8718-DEC-87	
ILEN	7	312-649-3338	N	4	0	0	0	7-APR-86	
ILIP	7	312-431-3600	N		0	1	0	21-DEC-8719-FEB-90	
ILLU	7	708-216-8000	N	4	0	2	1	7-APR-8625-FEB-92	
ILLV	7	312-649-3338	N	4	0	0	0	7-APR-86	
ILMM	7	217-782-5880	N	4	0	0	0	7-APR-8621-AUG-89	
ILMN	7	217-782-6080	N	4	0	0	0	7-APR-86	
ILNM	7	312-908-8900	N	4	0	17	20	7-APR-86 3-FEB-92	
ILPL	7	312-266-5888	N	4	0	0	5	7-APR-8629-DEC-89	
ILSF	7	309-655-2000	N	4	0	0	0	7-APR-8621-AUG-89	
ILSM	7	312-649-3338	N	4	0	0	0	7-APR-86	
ILUC	7	312-702-3000	N	4	0	0	0	20-JAN-92	
ILUI	7	312-996-6771	N	4	0	10	0	7-APR-8621-AUG-89	
ILVA	7	312-531-3000	N		0	0	0	31-AUG-8931-AUG-89	
INCI	10	317-924-8888	N	3	0	0	0	7-APR-86	
INDV	10	317-924-8888	N	3	0	0	0	7-APR-8619-NOV-86	
INEV	10	317-924-8888	N	3	0	0	0	7-APR-86 6-NOV-87	
INFW	10	317-924-8888	N	3	0	0	0	7-APR-86 6-NOV-87	
INHA	10	317-924-8888	N	3	0	0	0	7-APR-86 9-JUL-86	
INIM	10	317-924-8888	N	1	22	6	7	7-APR-8629-DEC-89	
INIU	10	317-924-8888	N	3	7	0	6	7-APR-8614-SEP-89	
INIV	10	317-924-8888	N	3	0	0	0	7-APR-86 8-JUL-87	
INLA	10	317-924-8888	N	3	0	0	0	7-APR-86 6-NOV-87	
INLF	10	317-924-8888	N	3	0	0	0	7-APR-8614-DEC-87	
INLH	10	317-924-8888	N	4	0	0	0	7-APR-8615-OCT-86	
INMU	10	317-924-8888	N	3	0	0	0	7-APR-86 6-NOV-87	
INOP	10	317-924-8888	N		0	0	0	23-DEC-87	
INSB	10	317-924-8888	N	3	0	0	0	7-APR-86 6-NOV-87	
INSV	10	317-924-8888	N	3	0	0	0	7-APR-86 6-NOV-87	
INTE	10	317-924-8888	N	3	0	0	0	7-APR-86 8-JUL-87	
INVA	10	317-924-8888	N	3	0	0	0	7-APR-86	
INVI	10	317-924-8888	N	3	0	0	0	7-APR-8614-DEC-87	
KSFT	8	800-366-6791	N	4	0	0	0	7-APR-86	
KSFV	8	800-366-6791	N	4	0	0	0	7-APR-8612-DEC-89	
KSUK	8	800-366-6791	N	4	0	0	0	7-APR-8629-MAY-90	
KYHH	11	800-525-3456	Y		0	0	0	21-JUL-92	
KYJH	11	800-525-3456	Y	1	46	38	40	7-APR-8615-OCT-90	
KYKC	11	800-525-3456	N	4	0	0	0	30-SEP-8730-SEP-87	
KYKY	11	800-525-3456	Y	1	12	3	3	30-SEP-87 7-FEB-89	48
KYUK	11	800-525-3456	Y	1	0	0	0	7-APR-86 1-DEC-87	20
KYUL	11	800-525-3456	N	3	0	0	0	7-APR-86 1-DEC-87	
KYWK	11	502-589-4148	N	4	0	0	0	7-APR-86	
LANO	3	504-464-3898	Y	1	22	20	53	7-APR-86 1-SEP-91	5
LAOF	3	504-842-3838	Y	1	3	5	11	7-APR-86 2-NOV-89	21
LAOP	3	504-837-3355	Y		0	0	0	17-MAR-88	17
LASB	3	504-837-3355	N	4	0	2	0	7-APR-8622-NOV-89	
LASM	3	318-227-4715	Y	4	0	0	0	7-APR-86 2-NOV-89	10
LASU	3	318-226-3589	Y	1	14	28	17	7-APR-86 2-NOV-89	-4
LATU	3	504-588-5303	Y	1	16	16	23	7-APR-8622-JUL-89	2
LAWK	3	318-226-3589	N		0	0	0	26-JUL-89 5-OCT-89	

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MABI	1	800-446-6362	N	4	0	0	0	7-APR-86
MABS	1	800-446-6362	N		0	0	0	20-OCT-88
MABU	1	800-446-6362	N	4	0	0	0	7-APR-86
MABV	1	800-446-6362	N	4	0	0	0	7-APR-86
MACH	1	800-446-6362	N	4	0	1	1	7-APR-8631-MAR-89
MAHS	1	800-446-6362	N	4	0	0	0	7-APR-86
MALC	1	800-446-6362	N	4	0	0	0	7-APR-86
MAMG	1	800-446-6362	N	4	0	3	1	7-APR-8610-JUL-89
MANM	1	800-446-6362	N	4	0	0	0	7-APR-86
MAPB	1	800-446-6362	N	4	0	0	0	7-APR-86
MAUM	1	800-446-6362	N	4	0	0	0	7-APR-86
MDBC	2	301-328-3626	N	2	0	0	0	7-APR-8612-NOV-90
MDJH	2	301-328-3626	N	2	62	47	59	7-APR-8612-NOV-90
MDPC	2	301-528-3626	N		0	0	0	12-NOV-9012-NOV-90
MDUM	2	301-328-3626	N	2	0	0	1	7-APR-8612-NOV-90
MEMC	1	800-446-6362	N	4	0	0	0	7-APR-86
METR	1	514-527-0047	N		0	0	0	5-DEC-86
MIAA	10	-	N		0	0	0	27-AUG-86
MIBH	10	313-973-1577	N	4	0	0	0	7-APR-86
MICH	10	313-973-1577	N	4	0	0	0	7-APR-86
MIHF	10	313-973-1577	N	4	0	2	5	7-APR-8628-DEC-89
MIHH	10	313-973-1577	N		0	0	0	25-OCT-90
MIHM	10	313-973-1577	N	4	0	0	0	7-APR-86
MIKZ	10	313-973-1577	N	4	0	4	0	7-APR-8610-JUL-89
MIMC	10	313-973-1577	N	4	0	1	1	7-APR-8610-MAY-89
MIMS	10	313-973-1577	N	4	0	0	0	7-APR-86
MIOP	10	3139731577	N					20-OCT-91
MISH	10	-	N	4	0	0	0	7-APR-86
MISJ	10	313-973-1577	N		0	0	0	2-JUL-90 2-JUL-90
MISM	10	313-973-1577	N	4	0	0	0	7-APR-86
MITS	10	313-973-1577	N	4	2	0	0	7-APR-8613-OCT-86
MIUM	10	313-973-1577	N	4	0	1	6	7-APR-8611-MAR-88
MIVA	10	313-973-1577	N	4	0	0	0	7-APR-86
MIWS	10	313-973-1577	N	4	0	0	0	7-APR-86
MNAN	7	612-874-5700	N		0	0	0	29-SEP-86 3-OCT-88
MNHC	7	612-347-5850	N	4	0	0	0	7-APR-86 3-OCT-88
MNMC	7	507-284-2511	N	4	0	0	0	7-APR-86 3-OCT-88
MNMG	7	612-347-5850	N	4	0	0	0	7-APR-86
MNMV	7	800-247-4273	N	4	0	0	0	7-APR-86
MNOP	7	800-247-4273	N		0	0	0	2-JUN-8829-JAN-92
MNSM	7	507-284-2511	N		0	0	0	8-NOV-90
MNTL	7	612-625-4979	N		0	0	0	29-DEC-88
MNUM	7	800-247-4273	N	4	0	3	7	7-APR-86 3-DEC-89
MOBH	8	800-333-6432	N	4	6	-2	2	7-APR-86 5-DEC-89
MOCG	8	800-333-6432	N		0	0	0	27-NOV-90
MOCH	8	800-333-6432	N	4	0	1	1	7-APR-8619-SEP-86
MOCM	8	800-366-6791						30-AUG-9106-SEP-91
MODU	8	800-333-6432	N		0	0	0	10-DEC-8722-JUN-89
MOJH	8	314-362-1242	N	4	0	0	0	7-APR-86
MOLH	8	800-366-6791	N	4	0	0	0	7-APR-8629-MAY-90
MOMA	8	800-333-6432	N		0	0	0	24-MAR-8815-JUL-88
MOMM	8	800-366-6791	N		0	0	0	6-JAN-88

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MORE	8416-595-3587	N		4	0	0	5-DEC-86 5-MAR-87	
MORH	8800-366-6791	N	4	0	0	0	7-APR-8629-MAY-90	
MOSL	8800-333-6432	N	4	0	0	0	7-APR-8615-JUL-88	
MOTS	8519-663-3000	N		0	0	0	5-DEC-86	
MOUM	8800-366-6791	N	4	0	1	1	7-APR-8626-AUG-86	
MSUM	3601-984-1000	Y	1	71	45	50	7-APR-8628-SEP-89	127
MWOB	8800-366-6791	N	4	1	0	0	7-APR-86 9-NOV-89	
MWWL	7800-446-2726	N		0	0	0	23-JUN-89	
NCBG	11800-833-3002	Y	1	8	4	1	7-APR-8615-DEC-89	35
NCBH	11919-748-4563	N	1	8	0	0	7-APR-8628-DEC-89	
NCCM	11704-355-2000	Y	1	42	36	67	7-APR-8631-AUG-90	-3
NCCP	11919-752-5480	N	1	31	34	80	7-APR-8616-DEC-89	
NCDU	11919-752-5480	Y	1	0	0	0	7-APR-8630-DEC-87	20
NCDV	11919-752-5480	N	3	0	0	0	7-APR-86	
NCEC	11919-752-5480	Y	1	0	0	0	7-APR-8630-DEC-87	20
NCMH	11919-752-5480	Y	1	0	0	0	7-APR-8630-DEC-87	20
NCNC	11919-752-5480	Y	1	87	71	71	29-JUN-8810-JAN-89	15
NCRC	11800-446-2726	N		0	0	0	25-MAR-88	
NDDH	7701-234-6000	N		0	0	0	8-JUN-89 2-NOV-89	
NDMC	7701-224-6000	N		0	0	0	14-OCT-8830-NOV-88	
NDSL	7701-234-6000	N		0	0	0	6-DEC-89	
NDTB	7701-222-5200	N	4	0	0	0	19-JAN-9026-MAR-90	
NDTC	7701-224-6000	N		0	0	0	19-JAN-90	
NDTS	7701-234-6000	N		0	0	0	18-OCT-89	
NEBM	8402-553-7952	N		0	0	0	7-FEB-89	
NECM	8402-553-7952	N		0	0	0	7-FEB-89	
NEOB	1800-446-6362	N	4	0	-3	0	7-APR-8630-DEC-88	
NEOR	8402-553-7952	N	4	0	0	0	7-APR-86	
NEOX	1800-446-6362	N	3	0	0	0	19-MAY-86	
NESJ	8402-553-7952	N	4	0	0	0	7-FEB-89 7-FEB-89	
NEUN	8402-553-7952	N		0	0	0	7-FEB-89	
NHDH	1800-446-6362	N		0	0	0	10-AUG-9230-DEC-88	
NJBI	2800-541-0075	N	3	34	1	44	7-APR-8626-MAR-90	
NJLL	2609-428-5999	N	3	9	8	8	7-APR-8628-NOV-89	
NJSB	2800-541-0075	N	4	24	23	20	7-APR-8620-APR-90	
NJSN	2201-379-4535	N		0	0	0	12-DEC-88	
NJTL	2800-541-0075	N		0	0	0	12-DEC-8818-JUN-90	
NJTO	2800-541-0075	N		0	0	0	10-APR-9018-JUN-90	
NJUH	2800-541-0075	N		0	0	0	13-FEB-8926-MAR-90	
NMAQ	5505-843-2111	Y	1	16	15	24	7-APR-8631-OCT-91	27
NMOP	5505-843-7672	Y		0	0	0	21-AUG-87	31
NMPH	5505-841-1234	N		0	0	0	5-SEP-8631-OCT-91	
NORS	8402-553-7952	N		0	36	0	4-SEP-8726-JUL-89	
NVHH	5702-796-9600	N		0	0	0	3-JUL-90 3-JUL-90	
NVLV	5702-796-9600	N		0	0	0	9-OCT-87 3-JUL-90	
NVUM	5702-796-9600	N		0	0	0	28-FEB-90 3-JUL-90	
NYAM	9518-381-7111	N	4	0	0	0	7-APR-86	
NYAP	9518-381-7111	N		0	0	0	12-DEC-89	
NYBC	9716-883-0003	N		0	0	0	9-JAN-91 9-JAN-91	
NYBU	9716-883-0003	N	4	0	0	0	7-APR-86 9-JAN-91	
NYCL	9212-870-2240	N		0	0	0	20-DEC-89	
NYCO	9212-541-8060	N		0	0	0	20-JUL-90	

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NYCP	9:212-870-2240	N	4	0	4	2	7-APR-8630-MAY-90	
NYDP	9:718-234-9700	N		0	0	0	13-NOV-87	
NYDS	9:212-870-2240	N	4	0	8	2	7-APR-86 1-MAY-88	
NYEC	9:716-883-0003	N		0	0	0	9-JAN-91 9-JAN-91	
NYFL	9:716-275-2729	N		0	0	0	22-APR-9222-APR-92	
NYIL	9:212-870-2240	N		0	0	0	26-OCT-8912-DEC-89	
NYMA	9:212-870-2240	N	4	0	0	0	7-APR-86 6-MAR-87	
NYMH	9:212-241-7344	N		0	0	0	28-JUN-8929-JUN-89	
NYMS	9:212-870-2240	N	4	0	1	1	7-APR-8610-OCT-86	
NYNY	9:212-870-2240	N	4	0	28	9	7-APR-8610-OCT-88	
NYRT	9:212-870-2240	N		0	0	0	1-FEB-88	
NYSB	9:516-689-8333	N	4	0	0	0	7-APR-8621-MAR-89	
NYSL	9:212-870-2240	N	4	0	0	0	7-APR-86	
NYSM	9:716-275-2729	N		0	0	0	24-APR-9222-APR-92	
NYUC	9:212-870-2240	N		0	0	0	1-NOV-88	
NYUM	9:315-464-5540	N	4	0	0	0	7-APR-86 2-DEC-89	
NYWC	9:212-870-2240	N		0	0	0	18-JUL-8931-OCT-89	
NYWN	9:716-883-0003	N	4	0	-9	0	7-APR-8624-OCT-89	
OC01	99:800-292-9537	N	4	0	0	0	21-APR-92	
OC02	99:800-292-9537	N	4				30-APR-92	
OC03	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC04	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC05	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC06	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC07	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC08	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC09	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC10	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC11	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC12	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC13	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC14	99:800-292-9537	N	4	0	0	0	30-APR-92	
OC15	99:800-292-9537	N	4	0	0	0	30-APR-92	
OHAC	10:216-791-5433	N	4	0	4	1	7-APR-8612-FEB-88	
OHCA	10:216-791-5433	N	4	0	0	0	7-APR-8616-MAY-88	
OHCC	10:216-791-5433	N	4	0	12	4	7-APR-8625-SEP-89	
OHCD	10:614-263-5667	N		0	0	0	8-JUN-88	
OHCH	10:614-263-5667	N	4	0	0	0	7-APR-86 9-FEB-87	
OHCM	10:513-558-5000	N		0	0	0	11-OCT-9020-FEB-91	
OHCO	10:419-893-4891	Y	1	17	8	10	7-APR-8631-MAY-89	20
OHCV	10:216-791-5433	N	4	0	0	0	7-APR-8630-AUG-86	
OHCW	10:800-558-5433	N	4	0	0	0	7-APR-8614-DEC-87	
OHDC	10:614-263-5667	N	4	0	0	0	7-APR-86 2-DEC-86	
OHDN	10:614-263-5667	N	4	0	0	0	7-APR-86	
OHLB	10:216-791-5433	N		0	0	0	26-OCT-87	
OHLC	10:513-223-1606	Y		0	0	0	8-MAR-90	38
OHLI	10:614-263-5667	N	4	0	0	0	7-APR-86 3-DEC-86	
OHLM	10:419-893-4891	N	1	0	0	0	7-APR-8622-MAR-88	
OHLP	10:614-263-5667	N		0	0	0	19-JUN-89	
OHMC	10:614-263-5667	Y	4	0	0	0	7-APR-86 2-DEC-86	0
OHMG	10:800-558-5433	N	4	0	0	0	7-APR-8614-DEC-87	
OHMI	10:614-263-5667	N	4	0	0	0	7-APR-86	

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OHMN	10	614-263-5667	N	4	0	0	0	7-APR-86 2-DEC-86	
OHMS	10	800-558-5433	N	4	0	0	0	7-APR-8614-DEC-87	
OHMV	10	513-223-1606	Y	1	36	16	34	7-APR-86 4-DEC-89	25
OHOC	10	614-591-68 1	N		0	0	0	16-NOV-8930-JAN-90	
OHOR	10	216-000-0000	N	4	0	0	0	7-APR-86	
OHOU	10	614-263-5667	N	4	0	7	0	7-APR-86 6-DEC-89	
OHPH	10	614-263-5667	N	4	0	0	0	7-APR-8626-MAY-89	
OHPM	10	614-263-5667	N	4	0	0	0	7-APR-86	
OHRH	10	614-263-5667	N	4	0	0	0	7-APR-86	
OHSE	10	216-791-5433	N		0	0	0	27-SEP-8823-APR-90	
OHSP	10	614-263-5667	N	4	0	0	0	7-APR-86	
OHSV	10	419-893-4891	N	1	0	0	0	7-APR-8622-MAR-88	
OHTC	10	513-558-5000	N					11-OCT-90	
OHTH	10	419-893-4891	N	4	0	0	0	7-APR-86	
OHTL	10	614-263-5667	N	4	0	0	0	7-APR-86 2-DEC-86	
OHUC	10	513-558-5000	N	3	3	12	22	7-APR-86 3-DEC-89	0
OHUH	10	216-791-5433	N		0	1	0	24-FEB-8824-JAN-89	
OHZA	10	614-263-5667	N	4	0	0	0	7-APR-86 9-FEB-87	
OKBC	4	405-840-5551	N		0	1	5	18-FEB-8711-JAN-89	
OKCM	4	405-840-5551	N	4	0	0	0	7-APR-8611-JUN-87	
OKHM	4	405-840-5551	N	4	0	1	1	7-APR-86 6-APR-92	
OKMD	4	405-840-5551	Y	4	0	0	0	7-APR-86 1-JUN-87	1
OKMH	4	405-271-4438	N	4	0	0	0	7-APR-86	
OKOP	4	405-840-5551	N		0	0	0	3-MAR-89 3-MAR-89	
OKOV	4	405-840-5551	N	4	0	7	0	7-APR-8613-APR-89	
OKSA	4	405-840-5551	Y	1	7	7	7	7-APR-8614-SEP-87	-4
OKTH	4	918-584-1351	N	4	0	0	0	7-APR-86	
ORUO	6	503-494-8555	N	4	0	1	0	7-APR-8630-APR-90	
PAAE	2	800-543-6391	N	4	0	0	0	7-APR-86	
PAAG	2	800-366-6777	N	3	0	-1	0	26-OCT-8720-DEC-89	
PACH	2	800-366-6777	N		0	0	0	27-OCT-8718-AUG-89	
PACP	2	800-543-6391	N		0	0	0	28-SEP-8813-JAN-89	
PADV	2	800-543-6391	N		0	0	0	21-FEB-88	
PAGM	2	800-543-6391	N	4	0	1	0	7-APR-8623-JAN-89	
PAHE	2	800-543-6391	N	4	0	20	11	7-APR-8628-DEC-88	
PAHM	2	800-543-6391	N	4	0	0	0	7-APR-86	
PALV	2	800-543-6391	N		0	0	0	8-MAY-91	
PAPT	2	800-366-6777	N	3	0	18	68	7-APR-86 5-JAN-90	
PASC	2	800-543-6391	N	4	0	6	4	7-APR-8616-AUG-88	
PATF	2	800-366-6777	N		0	2	0	26-OCT-8717-AUG-89	
PATJ	2	800-543-6391	N	4	0	-9	6	7-APR-86 9-MAR-89	
PATU	2	800-543-6391	N		0	0	0	7-MAY-87	
PAUF	2	800-543-6391	N	4	0	0	0	7-APR-86	
PAUP	2	800-543-6391	N	4	0	25	0	7-APR-8623-JAN-89	
PRSJ	3	809-758-2000	N	4	0	1	4	7-APR-8614-DEC-87	
PRUA	3	809-758-7575	N	4	0	0	0	7-APR-86	
PRVA	3	809-758-2000	N		0	0	0	23-SEP-86	
ROPA	5	310-825-7651	N	4	1	9	27	7-APR-86 5-NOV-91	
SCDF	11	- -	N		0	0	0	25-AUG-86	
SCKC	11	- -	N		0	0	0	25-AUG-86	
SCMU	11	803-724-5563	Y	2	10	5	17	7-APR-8617-OCT-89	-29
SCOP	11	803-724-5563	N		0	0	0	5-APR-88	

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SCWC	11	-	N		0	0	0	25-AUG-86	
SEOP	2	804-755-1615	N	4	0	0	0	7-APR-86 3-OCT-88	
TESQ	1	800-555-5555	N		0	0	0	16-OCT-87	
TNBM	11	901-522-5055	N		0	0	0	3-MAR-88	
TNDC	11	615-327-2247	Y	1	39	20	29	7-APR-8620-DEC-90	
TNDS	11	615-327-2247	Y		0	0	0	2-JUN-8811-JAN-91	43
TNEM	11	615-757-1006	Y		0	0	0	19-OCT-89	34
TNET	11	615-929-1141	Y		0	0	0	8-SEP-88	137
TNJC	11	615-926-3112	Y					22-AUG-9008-JUL-91	113
TNMH	11	901-528-5923	N		0	0	0	14-OCT-8714-OCT-87	
TNMS	11	901-577-5923	Y		0	0	0	3-JAN-91	-32
TNNV	11	615-321-3003	Y	1	14	10	7	7-APR-8614-NOV-89	0
TNPV	11	615-321-3003	Y		0	0	0	23-JUN-89 2-NOV-89	-23
TNST	11	615-327-2247	Y	1	0	0	0	7-APR-8620-JUL-90	13
TNTN	11	615-327-2247	Y		0	0	0	27-OCT-9211-JAN-91	43
TNUK	11	615-544-9881	Y	1	35	14	46	7-APR-8627-DEC-89	-8
TNUT	11	901-528-5923	Y	1	48	29	57	7-APR-86 5-JAN-90	-2
TNVU	11	615-321-3003	Y	1	17	8	16	7-APR-8614-NOV-89	-50
TOFA	5	619-933-3333	N	4	0	0	0	7-APR-86	
TXAD	4	512-459-4848	N	4	0	0	0	7-APR-8612-AUG-92	
TXAV	4	512-732-9612	N	4	0	0	0	7-APR-86	
TXBC	4	512-732-9612	Y	3	0	2	4	7-APR-8614-DEC-88	-4
TXBU	4	214-821-1910	N		0	0	0	29-DEC-88	
TXCM	4	214-821-1910	N	4	0	1	0	7-APR-86 3-JAN-90	
TXCT	4	512-459-1111	N	0	0	0	0	6-NOV-90	
TXDR	4	512-732-9612	N	4	0	0	0	7-APR-86	
TXEA	4	512-732-9612	N	4	0	0	0	7-APR-86	
TXEP	4	800-666-1884	N		0	0	0	26-FEB-90	
TXFW	4	817-870-0060	N	4	0	0	0	7-APR-86 4-MAR-87	
TXGC	4	713-799-9115	N		0	0	0	16-OCT-8714-JAN-88	
TXHD	4	512-732-9612	N		0	0	0	6-MAR-90	
TXHH	4	713-799-9115	N	3	3	10	10	7-APR-8613-JAN-88	
TXHI	4	713-799-9115	N		0	0	0	31-MAR-8714-JAN-88	
TXHS	4	512-732-9612	N		0	4	8	25-JAN-9025-JAN-90	
TXHT	4	214-821-4284	N	4	0	0	0	7-APR-86	
TXJL	4	409-762-2560	N		0	0	0	30-AUG-8912-OCT-89	
TXJS	4	409-762-2560	N	4	0	1	1	7-APR-8610-OCT-86	
TXKD	4	512-732-9612	N	4	0	0	0	7-APR-86	
TXLA	4	512-732-9612	N	4	0	0	0	7-APR-86	
TXLG	4	806-744-4499	N		0	0	0	14-APR-88 9-DEC-91	
TXLM	4	806-744-4499	N		0	0	0	2-JUL-90 9-DEC-91	
TXMC	4	214-821-1910	N	4	0	-5	0	7-APR-86 5-JAN-90	
TXMH	4	713-799-9115	N	3	3	3	35	7-APR-8614-DEC-88	
TXPM	4	214-821-1910	N	4	0	11	3	7-APR-8624-MAR-87	
TXSA	4	512-732-9612	N	4	0	0	0	11-SEP-86	
TXSB	4	214-821-1910	N		0	0	0	8-SEP-88	
TXSH	4	512-732-9616	N	4	0	0	0	7-APR-86	
TXSM	4	915-546-6009	N		0	0	0	29-MAR-8829-MAR-88	
TXSP	4	214-821-1910	N	4	0	0	0	7-APR-86	
TXSR	4	512-732-9612	N	4	0	0	0	7-APR-86	
TXST	4	512-732-9612	Y	4	0	0	0	7-APR-86	0
TXSW	4	214-821-1910	N		0	0	0	18-DEC-87	

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TXTC	4	713-799-9115	N		0	0	0	11-AUG-88	
TXTL	4	214-688-3556	N		0	0	0	23-AUG-88	
TXTX	4	214-821-1910	N	4	0	-15	12	7-APR-86 7-JUN-89	
TXTY	4	903-597-6445	N		0	0	0	29-APR-8822-NOV-91	
TXUT	4	-	N	3	0	0	0	7-APR-86	
TXVU	4	512-732-9612	N	4	0	0	0	7-APR-86	
TXWA	4	512-732-9612	N	4	0	0	0	7-APR-86	
TXWH	4	512-732-9612	N	4	0	0	0	7-APR-86	
UNOS	99	800-292-9537	N	4	0	0	0	13-OCT-8714-APR-92	
UTAH	5	800-833-6667	N	4	0	0	0	7-APR-86 5-JAN-87	
UTLD	5	800-833-6667	N	4	2	1	0	7-APR-8631-MAY-88	
UTLS	5	801-321-1234	N	4	0	0	0	7-APR-86	
UTMC	5	800-833-6667	N	4	0	0	0	7-APR-86 3-MAR-88	
UTOP	5	800-833-6667	N		0	0	0	18-NOV-87 8-AUG-88	
UTPC	5	800-833-6667	N		0	0	0	3-DEC-91 3-DEC-91	
UTVA	5	800-833-6667	N	1	0	0	0	4-OCT-91 4-OCT-91	
VAFH	2	202-223-8229	N		0	0	0	27-APR-8728-MAR-88	
VAFP	11	703-698-3158	N		0	0	0	27-OCT-87	
VAHD	11	804-771-9282	Y		0	0	0	10-AUG-89	10
VAKD	11	804-771-9282	N		0	0	0	10-AUG-89	
VALD	11	804-628-3906	N	3	0	0	0	7-APR-86	
VAMC	11	804-771-9282	Y	1	10	15	15	7-APR-8622-JAN-90	-6
VAMV	11	804-771-9282	N	1	0	0	0	7-APR-86 4-MAY-88	
VANG	11	804-628-3906	Y	1	25	107	66	7-APR-86 3-JAN-90	-4
VAOP	11	703-772-1408	Y		0	0	0	21-JUN-88	3
VAPG	11	804-628-3906	N	3	0	0	0	7-APR-86	
VARH	11	804-628-3906	N	3	0	0	0	7-APR-86	
VATB	11	804-771-9282	Y		0	0	0	27-OCT-8722-JUN-88	0
VAUV	11	804-924-0000	Y	1	15	4	4	7-APR-86 3-DEC-89	-10
VTMC	1	800-446-6362	N	4	0	0	0	7-APR-86	
WACH	6	206-292-2795	N		0	0	0	9-JAN-90	
WANW	6	206-292-2795	N	4	0	24	4	7-APR-86 2-JAN-90	
WASH	6	509-455-3131	N		0	0	0	11-JUN-87	
WASM	6	206-292-2795	N		0	0	0	20-FEB-9223-APR-92	
WAUW	6	206-292-2795	N		0	0	0	9-JAN-90	
WAVM	6	206-292-2795	N		0	0	0	9-MAY-91	
WICH	7	800-432-5405	N		0	0	0	18-DEC-91	
WIMC	7	800-432-5405	N		0	0	0	21-APR-9218-MAY-90	
WIOP	7	000-000-0000	N		0	0	0	14-MAR-89	
WISE	7	800-432-5405	N	3	0	2	5	7-APR-8618-MAY-90	
WISL	7	414-649-3700	N	4	0	0	0	7-APR-86	
WIUW	7	608-262-0143	N		0	11	10	20-DEC-89	
WVCA	2	800-366-6777	N		0	0	0	14-MAR-8825-FEB-92	
WVCC	2	614-263-5667	N	4	0	0	0	7-APR-8620-OCT-87	
WVMS	2	800-634-4414	N		0	0	0	27-OCT-87	
WVWU	2	800-366-6777	N	4	0	0	0	7-APR-86 7-OCT-88	

OIS Universal Donor Programs

The OIS Universal Donor programs need to be modified to:

- Accept data from the Mainframe Gateway Server program.
- Break up Match Run results by organ.
- Write the Match Run results with the proper OIS header record for each organ to a file in a network shared directory.

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Medical/Social History	CancerSite	1	Skin	CNLOC
Medical/Social History	CancerSite	2	Colo-Rectal	CNLOC
Medical/Social History	CancerSite	3	Genito-Urinary	CNLOC
Medical/Social History	CancerSite	4	Leukemia/Lymphoma	CNLOC
Medical/Social History	CancerSite	5	Breast	CNLOC
Medical/Social History	CancerSite	999	Other, Specify	CNLOC
Organ Recovery	RecoveryReasonCode	REC	Recovered Organ	RCVR
Organ Recovery	RecoveryReasonCode	200	Poor Organ Function	RCVR
Organ Recovery	RecoveryReasonCode	201	Cardiac Arrest	RCVR
Organ Recovery	RecoveryReasonCode	202	Infection	RCVR
Organ Recovery	RecoveryReasonCode	203	Positive Hepatitis	RCVR
Organ Recovery	RecoveryReasonCode	204	Positive Hiv	RCVR
Organ Recovery	RecoveryReasonCode	205	Diseased Organ	RCVR
Organ Recovery	RecoveryReasonCode	206	Anatomical Abnormalities	RCVR
Organ Recovery	RecoveryReasonCode	207	Vascular Damage	RCVR
Organ Recovery	RecoveryReasonCode	208	No Recipient Located	RCVR
Organ Recovery	RecoveryReasonCode	209	Donor Medical History	RCVR
Organ Recovery	RecoveryReasonCode	210	Donor Social History	RCVR
Organ Recovery	RecoveryReasonCode	211	Positive Htiv - 1	RCVR
Organ Recovery	RecoveryReasonCode	212	Biopsy Findings	RCVR
Organ Recovery	RecoveryReasonCode	295	Donor History, Undetermined, Medical Or S	RCVR
Organ Recovery	RecoveryReasonCode	298	Unknown	RCVR
Organ Recovery	RecoveryReasonCode	299	Other, Specify	RCVR
Organ Recovery	DiscardReasonCode	601	Too Old On Pump	DCRD
Organ Recovery	DiscardReasonCode	602	Too Old On Ice	DCRD
Organ Recovery	DiscardReasonCode	603	Vascular Damage	DCRD
Organ Recovery	DiscardReasonCode	604	Ureteral Damage	DCRD
Organ Recovery	DiscardReasonCode	605	Inadequate Urine Output	DCRD
Organ Recovery	DiscardReasonCode	606	Donor Medical History	DCRD
Organ Recovery	DiscardReasonCode	607	Donor Social History	DCRD
Organ Recovery	DiscardReasonCode	608	Positive Cmv	DCRD
Organ Recovery	DiscardReasonCode	609	Positive Hiv	DCRD
Organ Recovery	DiscardReasonCode	610	Positive Hepatitis	DCRD
Organ Recovery	DiscardReasonCode	611	Warm Ischemic Time Too Long	DCRD
Organ Recovery	DiscardReasonCode	612	Organ Trauma	DCRD

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Organ Recovery	DiscardReasonCode	613	Organ Not As Described	DCRD
Organ Recovery	DiscardReasonCode	614	Biopsy Findings	DCRD
Organ Recovery	DiscardReasonCode	615	Recip Determined To Be Unsuitable	DCRD
Organ Recovery	DiscardReasonCode	698	Unknown	DCRD
Organ Recovery	DiscardReasonCode	699	Other, Specify On Form	DCRD
Organ Recovery	DispositionCode	501	Organ Transplanted Locally	DSPN
Organ Recovery	DispositionCode	502	Organ Transplanted Shared	DSPN
Organ Recovery	DispositionCode	503	Organ Was Discarded Locally	DSPN
Organ Recovery	DispositionCode	504	Organ Was Shared And Discarded	DSPN
Organ Recovery	DispositionCode	505	Organ Was Submitted For Research	DSPN
Organ Recovery	DispositionCode	506	Heart Procured For Valves Only	DSPN
Organ Recovery	DispositionCode	507	Organ Exported Outside U.S.	DSPN
Organ Recovery	DispositionCode	508	Pancreas Islet Cells	DSPN
Organ Recovery	DispositionCode	509	Extra-Corporeal Liver	DSPN
Organ Recovery	FlushSolution	300	Viospan (UW/Belzer)	FLSN
Organ Recovery	FlushSolution	301	Eurocollins	FLSN
Organ Recovery	FlushSolution	302	Modified Collins	FLSN
Organ Recovery	FlushSolution	303	Cardioplege	FLSN
Organ Recovery	FlushSolution	304	Pulmoplege	FLSN
Organ Recovery	FlushSolution	398	Unknown	FLSN
Organ Recovery	FlushSolution	399	Other, Specify	FLSN
Organ Recovery	StorageSolution	400	Viospan (UW/Belzer)	STOR
Organ Recovery	StorageSolution	401	Eurocollins	STOR
Organ Recovery	StorageSolution	402	Modified Collins	STOR
Organ Recovery	StorageSolution	403	Saline	STOR
Organ Recovery	StorageSolution	404	Ringers	STOR
Organ Recovery	StorageSolution	498	Unknown	STOR
Organ Recovery	StorageSolution	499	Other, Specify	STOR
Organ Recovery	PlacedBy	1	Local	PLBY
Organ Recovery	PlacedBy	2	UNOS	PLBY
Organ Recovery	ShareType	1	6 Antigen Match	ORSH
Organ Recovery	ShareType	2	Payback	ORSH
Organ Recovery	ShareType	3	Non-Mandatory Share	ORSH
Organ Recovery	DurationCode	1	0 - 5 Years	DURTN
Organ Recovery	DurationCode	2	6 - 10 Years	DURTN

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Organ Recovery	DurationCode	3	Greater Than 10 Years	DURTN
Donor Information	State	AL	Alabama	STATE
Donor Information	State	AK	Alaska	STATE
Donor Information	State	AZ	Arizona	STATE
Donor Information	State	AR	Arkansas	STATE
Donor Information	State	CA	California	STATE
Donor Information	State	CO	Colorado	STATE
Donor Information	State	CT	Connecticut	STATE
Donor Information	State	DE	Delaware	STATE
Donor Information	State	DC	Dist. Of Columbia	STATE
Donor Information	State	FL	Florida	STATE
Donor Information	State	GA	Georgia	STATE
Donor Information	State	GU	Guam	STATE
Donor Information	State	HI	Hawaii	STATE
Donor Information	State	ID	Idaho	STATE
Donor Information	State	IL	Illinois	STATE
Donor Information	State	IN	Indiana	STATE
Donor Information	State	IA	Iowa	STATE
Donor Information	State	KS	Kansas	STATE
Donor Information	State	KY	Kentucky	STATE
Donor Information	State	LA	Louisiana	STATE
Donor Information	State	ME	Maine	STATE
Donor Information	State	MD	Maryland	STATE
Donor Information	State	MA	Massachusetts	STATE
Donor Information	State	MI	Michigan	STATE
Donor Information	State	MN	Minnesota	STATE
Donor Information	State	MS	Mississippi	STATE
Donor Information	State	MO	Missouri	STATE
Donor Information	State	MT	Montana	STATE
Donor Information	State	NE	Nebraska	STATE
Donor Information	State	NV	Nevada	STATE
Donor Information	State	NH	New Hampshire	STATE
Donor Information	State	NJ	New Jersey	STATE
Donor Information	State	NM	New Mexico	STATE
Donor Information	State	NY	New York	STATE

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Donor Information	State	NC	North Carolina	STATE
Donor Information	State	ND	North Dakota	STATE
Donor Information	State	OH	Ohio	STATE
Donor Information	State	OK	Oklahoma	STATE
Donor Information	State	OR	Oregon	STATE
Donor Information	State	PA	Pennsylvania	STATE
Donor Information	State	PR	Puerto Rico	STATE
Donor Information	State	RI	Rhode Island	STATE
Donor Information	State	SC	South Carolina	STATE
Donor Information	State	SD	South Dakota	STATE
Donor Information	State	TN	Tennessee	STATE
Donor Information	State	TX	Texas	STATE
Donor Information	State	UT	Utah	STATE
Donor Information	State	VT	Vermont	STATE
Donor Information	State	VA	Virginia	STATE
Donor Information	State	VI	Virgin Islands	STATE
Donor Information	State	WA	Washington	STATE
Donor Information	State	WV	West Virginia	STATE
Donor Information	State	WI	Wisconsin	STATE
Donor Information	State	WY	Wyoming	STATE
Donor Information	State	NA	Foreign Country	STATE
Donor Information	State	ZZ	Unknown	STATE
Consent Information	OrganConsentReason	100	Emotional	OCNS
Consent Information	OrganConsentReason	101	Racial/Ethnic	OCNS
Consent Information	OrganConsentReason	102	Religious	OCNS
Consent Information	OrganConsentReason	198	Unknown	OCNS
Consent Information	OrganConsentReason	199	Other, Specify	OCNS
Case Information	TimeZone	1	Eastern	TMZN
Case Information	TimeZone	2	Central	TMZN
Case Information	TimeZone	3	Mountain	TMZN
Case Information	TimeZone	4	Pacific	TMZN
Case Information	TimeZone	5	Alaska	TMZN
Case Information	TimeZone	6	Hawaii	TMZN
Lab Data	Serology	P	Positive	SRLG
Lab Data	Serology	N	Negative	SRLG

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Lab Data	Serology	U	Unknown	SRLG
Lab Data	Serology	C	Cannot Disclose	SRLG
Lab Data	Serology	ND	Not Done	SRLG
Lab Data	Serology	I	Indeterminate	
Lab Data	Medications		Ampicillin	
Lab Data	Medications		Ancel	
Lab Data	Medications		Benadryl	
Lab Data	Medications		Carapate	
Lab Data	Medications		Cefaclor	
Lab Data	Medications		Cefadyl	
Lab Data	Medications		Clindamycin	
Lab Data	Medications		DDAVP	
Lab Data	Medications		Decadron	
Lab Data	Medications		Dilantin	
Lab Data	Medications		Gentamicin	
Lab Data	Medications		Insulin	
Lab Data	Medications		Kefzol	
Lab Data	Medications		Lasix	
Lab Data	Medications		Levothyroxine	
Lab Data	Medications		Mannitol	
Lab Data	Medications		Methicillin	
Lab Data	Medications		Nafcillin	
Lab Data	Medications		Oxacillin	
Lab Data	Medications		Phenobarbital	
Lab Data	Medications		Pitressin	
Lab Data	Medications		Potassium Chloride	
Lab Data	Medications		Soluortef	
Lab Data	Medications		Solumedrol	
Lab Data	Medications		Thyroxine	
Lab Data	Medications		Ticarcillin	
Lab Data	Medications		Valium	
Lab Data	Medications		Verapamil	
Lab Data	Medications		Zantac	
Lab Data	Medications		Aramine	
Lab Data	Medications		Dobutamin	

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Lab Data	Medications		Dopamine	
Lab Data	Medications		Epinephrine	
Lab Data	Medications		Leuophed	
Lab Data	Medications		Neosynephrine	
Intraoperative Management	BloodProducts		Packed Red Blood Cells	
Intraoperative Management	BloodProducts		Platelets	
Intraoperative Management	BloodProducts		Fresh Frozen Plasma	
Intraoperative Management	BloodProducts		White Blood Cells	
Intraoperative Management	BloodProducts		Albumin 25%	
Intraoperative Management	BloodProducts		Albumin 5%	
Consent Information	Relationship	1	Parent	RLTYP
Consent Information	Relationship	2	Child	RLTYP
Consent Information	Relationship	3	Identical Twin	RLTYP
Consent Information	Relationship	4	Full Sibling	RLTYP
Consent Information	Relationship	5	Half Sibling	RLTYP
Consent Information	Relationship	6	Other Relative	RLTYP
Consent Information	Relationship	7	Spouse, Unrelated	RLTYP
Consent Information	Relationship	998	Unknown	RLTYP
Consent Information	Relationship	999	Other, Unrelated	RLTYP
Case Information	OrganType	HR	Heart	
Case Information	OrganType	KI	Kidney	
Case Information	OrganType	LI	Liver	
Case Information	OrganType	LU	Lung	
Case Information	OrganType	PA	Pancreas	
Case Information	OrganType	IN	Intestine	
Case Information	OrganType	HL	Heart/Lung	
Case Information	OrganType	PI	Pancreas Islets	
Case Information	OrganType	AL	All Organs	
Match Run	SEOPF		ALOB	
Match Run	SEOPF		ALUA	
Match Run	SEOPF		COMH	
Match Run	SEOPF		COPM	
Match Run	SEOPF		CORS	
Match Run	SEOPF		COSL	
Match Run	SEOPF		COUC	

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Match Run	SEOPF		FLAC	
Match Run	SEOPF		FLFH	
Match Run	SEOPF		FLFL	
Match Run	SEOPF		FLFR	
Match Run	SEOPF		FLJM	
Match Run	SEOPF		FLJT	
Match Run	SEOPF		FLMP	
Match Run	SEOPF		FLSF	
Match Run	SEOPF		FLSW	
Match Run	SEOPF		FLTG	
Match Run	SEOPF		FLUF	
Match Run	SEOPF		GAEH	
Match Run	SEOPF		GAEM	
Match Run	SEOPF		GALL	
Match Run	SEOPF		GAMC	
Match Run	SEOPF		GAPH	
Match Run	SEOPF		KYHH	
Match Run	SEOPF		KYJH	
Match Run	SEOPF		KYKY	
Match Run	SEOPF		KYUK	
Match Run	SEOPF		LANO	
Match Run	SEOPF		LAOF	
Match Run	SEOPF		LAOP	
Match Run	SEOPF		LASM	
Match Run	SEOPF		LASU	
Match Run	SEOPF		LATU	
Match Run	SEOPF		MSUM	
Match Run	SEOPF		NCBG	
Match Run	SEOPF		NCCM	
Match Run	SEOPF		NCDU	
Match Run	SEOPF		NCEC	
Match Run	SEOPF		NCMH	
Match Run	SEOPF		NCNC	
Match Run	SEOPF		NMAQ	
Match Run	SEOPF		NMOP	

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Match Run	SEOPF		OHCO	
Match Run	SEOPF		OHLC	
Match Run	SEOPF		OHMC	
Match Run	SEOPF		OHMV	
Match Run	SEOPF		OKMD	
Match Run	SEOPF		OKSA	
Match Run	SEOPF		SCMU	
Match Run	SEOPF		TNDC	
Match Run	SEOPF		TNDS	
Match Run	SEOPF		TNEM	
Match Run	SEOPF		TNET	
Match Run	SEOPF		TNJC	
Match Run	SEOPF		TNMS	
Match Run	SEOPF		TNNV	
Match Run	SEOPF		TNPV	
Match Run	SEOPF		TNST	
Match Run	SEOPF		TNTN	
Match Run	SEOPF		TNUK	
Match Run	SEOPF		TNUT	
Match Run	SEOPF		TNVU	
Match Run	SEOPF		TXBC	
Match Run	SEOPF		TXST	
Match Run	SEOPF		VAHD	
Match Run	SEOPF		VAMC	
Match Run	SEOPF		VANG	
Match Run	SEOPF		VAOP	
Match Run	SEOPF		VATB	
Match Run	SEOPF		VAUV	
Match Run	HighGradeSEOPF		KYKY	
Match Run	HighGradeSEOPF		GAMC	
Match Run	HighGradeSEOPF		OHLC	
Match Run	HighGradeSEOPF		VAOP	
Match Run	HighGradeSEOPF		VARM	
Match Run	HighGradeSEOPF		VAUV	
Match Run	HighGradeSEOPF		FLAC	

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Match Run	HighGradeSEOPF		FLFH	
Match Run	HighGradeSEOPF		FLFL	
Match Run	HighGradeSEOPF		FLFR	
Match Run	HighGradeSEOPF		FLJM	
Match Run	HighGradeSEOPF		FLJT	
Match Run	HighGradeSEOPF		FLMP	
Match Run	HighGradeSEOPF		FLSF	
Match Run	HighGradeSEOPF		FLSW	
Match Run	HighGradeSEOPF		FLTG	
Match Run	HighGradeSEOPF		FLUF	
Match Run	HighGradeSEOPF		NCBG	
Match Run	HighGradeSEOPF		NCCM	
Match Run	HighGradeSEOPF		NCDU	
Match Run	HighGradeSEOPF		NCEC	
Match Run	HighGradeSEOPF		NCMH	
Match Run	HighGradeSEOPF		NCNC	
Match Run	HighGradeSEOPF		TNDC	
Match Run	HighGradeSEOPF		TNDS	
Match Run	HighGradeSEOPF		TNEM	
Match Run	HighGradeSEOPF		TNET	
Match Run	HighGradeSEOPF		TNJC	
Match Run	HighGradeSEOPF		TNMS	
Match Run	HighGradeSEOPF		TNNV	
Match Run	HighGradeSEOPF		TNPV	
Match Run	HighGradeSEOPF		TNST	
Match Run	HighGradeSEOPF		TNTN	
Match Run	HighGradeSEOPF		TNUK	
Match Run	HighGradeSEOPF		TNUT	
Match Run	HighGradeSEOPF		TNVU	
Match Run	Region6		ORUO	
Match Run	Region6		WACH	
Match Run	Region6		WANW	
Match Run	Region6		WASH	
Match Run	Region6		WASM	
Match Run	Region6		WAUW	

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Match Run	Region6		WAVM	
Tray Data	CellValue	1	1-10%	
Tray Data	CellValue	2	11-20%	
Tray Data	CellValue	4	21-50%	
Tray Data	CellValue	6	51-80%	
Tray Data	CellValue	8	81-100%	
Tray Data	CellValue	0	Not Readable	
Tray Data	NYCellValue	+	Positive	
Tray Data	NYCellValue	-	Negative	
Donor Information	AHLA	1		AHLA
Donor Information	AHLA	2		AHLA
Donor Information	AHLA	203		AHLA
Donor Information	AHLA	210		AHLA
Donor Information	AHLA	3		AHLA
Donor Information	AHLA	9		AHLA
Donor Information	AHLA	10		AHLA
Donor Information	AHLA	11		AHLA
Donor Information	AHLA	19		AHLA
Donor Information	AHLA	23		AHLA
Donor Information	AHLA	24		AHLA
Donor Information	AHLA	2403		AHLA
Donor Information	AHLA	25		AHLA
Donor Information	AHLA	26		AHLA
Donor Information	AHLA	28		AHLA
Donor Information	AHLA	29		AHLA
Donor Information	AHLA	30		AHLA
Donor Information	AHLA	31		AHLA
Donor Information	AHLA	32		AHLA
Donor Information	AHLA	33		AHLA
Donor Information	AHLA	34		AHLA
Donor Information	AHLA	36		AHLA
Donor Information	AHLA	43		AHLA
Donor Information	AHLA	66		AHLA
Donor Information	AHLA	68		AHLA
Donor Information	AHLA	69		AHLA

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Donor Information	AHLA	74		AHLA
Donor Information	AHLA	80		AHLA
Donor Information	AHLA	95		AHLA
Donor Information	AHLA	96		AHLA
Donor Information	AHLA	97		AHLA
Donor Information	AHLA	98		AHLA
Donor Information	AHLA	99		AHLA
Donor Information	BHLA	5		BHLA
Donor Information	BHLA	7		BHLA
Donor Information	BHLA	703		BHLA
Donor Information	BHLA	8		BHLA
Donor Information	BHLA	12		BHLA
Donor Information	BHLA	13		BHLA
Donor Information	BHLA	14		BHLA
Donor Information	BHLA	15		BHLA
Donor Information	BHLA	16		BHLA
Donor Information	BHLA	17		BHLA
Donor Information	BHLA	18		BHLA
Donor Information	BHLA	21		BHLA
Donor Information	BHLA	22		BHLA
Donor Information	BHLA	27		BHLA
Donor Information	BHLA	35		BHLA
Donor Information	BHLA	37		BHLA
Donor Information	BHLA	38		BHLA
Donor Information	BHLA	39		BHLA
Donor Information	BHLA	3901		BHLA
Donor Information	BHLA	3902		BHLA
Donor Information	BHLA	40		BHLA
Donor Information	BHLA	4005		BHLA
Donor Information	BHLA	41		BHLA
Donor Information	BHLA	42		BHLA
Donor Information	BHLA	44		BHLA
Donor Information	BHLA	45		BHLA
Donor Information	BHLA	46		BHLA
Donor Information	BHLA	47		BHLA

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Donor Information	BHLA	48		BHLA
Donor Information	BHLA	49		BHLA
Donor Information	BHLA	50		BHLA
Donor Information	BHLA	51		BHLA
Donor Information	BHLA	5102		BHLA
Donor Information	BHLA	5103		BHLA
Donor Information	BHLA	52		BHLA
Donor Information	BHLA	53		BHLA
Donor Information	BHLA	54		BHLA
Donor Information	BHLA	55		BHLA
Donor Information	BHLA	56		BHLA
Donor Information	BHLA	57		BHLA
Donor Information	BHLA	58		BHLA
Donor Information	BHLA	59		BHLA
Donor Information	BHLA	60		BHLA
Donor Information	BHLA	61		BHLA
Donor Information	BHLA	62		BHLA
Donor Information	BHLA	63		BHLA
Donor Information	BHLA	64		BHLA
Donor Information	BHLA	65		BHLA
Donor Information	BHLA	67		BHLA
Donor Information	BHLA	70		BHLA
Donor Information	BHLA	71		BHLA
Donor Information	BHLA	72		BHLA
Donor Information	BHLA	73		BHLA
Donor Information	BHLA	75		BHLA
Donor Information	BHLA	76		BHLA
Donor Information	BHLA	77		BHLA
Donor Information	BHLA	7801		BHLA
Donor Information	BHLA	95		BHLA
Donor Information	BHLA	96		BHLA
Donor Information	BHLA	97		BHLA
Donor Information	BHLA	98		BHLA
Donor Information	BHLA	99		BHLA
Donor Information	DRHLA	1		DRHLA

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OIS Lookup Lists

Functional Area	List Name	Code	Description	OTIS Table Name
Donor Information	DRHLA	103		DRHLA
Donor Information	DRHLA	2		DRHLA
Donor Information	DRHLA	3		DRHLA
Donor Information	DRHLA	4		DRHLA
Donor Information	DRHLA	5		DRHLA
Donor Information	DRHLA	6		DRHLA
Donor Information	DRHLA	7		DRHLA
Donor Information	DRHLA	8		DRHLA
Donor Information	DRHLA	9		DRHLA
Donor Information	DRHLA	10		DRHLA
Donor Information	DRHLA	11		DRHLA
Donor Information	DRHLA	12		DRHLA
Donor Information	DRHLA	13		DRHLA
Donor Information	DRHLA	14		DRHLA
Donor Information	DRHLA	1403		DRHLA
Donor Information	DRHLA	1404		DRHLA
Donor Information	DRHLA	15		DRHLA
Donor Information	DRHLA	16		DRHLA
Donor Information	DRHLA	17		DRHLA
Donor Information	DRHLA	18		DRHLA
Donor Information	DRHLA	95		DRHLA
Donor Information	DRHLA	96		DRHLA
Donor Information	DRHLA	97		DRHLA
Donor Information	DRHLA	98		DRHLA
Donor Information	DRHLA	99		DRHLA

Appendix

Match Run Record Layout

Donor Match Run Record

Description	Match Run Record	Field Length	Comments
Donor Center Code	DCENTER	4	Validate Center Code
UNOS ID	DONID	6	Never Entered
User initials	USERID	2	Person entering the data
Donor Name	DONNAME	12	
Donor Age	DAGE	2	
Donor Age Unit	DAGEUNIT	1	M, Y
Donor Sex	DSEX	1	M, F
Donor Race	DRACE	1	B or N, W or C, I, O M or A, L
Donor ABO	DABO	2	A, B, AB, O for livers A1 or A2 subtyping must be specified for an A donor.
A Locus	DA1	2	lookup - Must have at least one from each low side. 0 for a blank. Only required for KI, PA, KI/PA, and PA/IN
A Equivalent	DA2	2	lookup
B Locus	DB1	2	lookup
B Equivalent	DB2	2	lookup
DR Locus	DDR1	2	lookup
DR Equivalent	DDR2	2	lookup
Organs	ORG1	2	HR, HL, KI, LI, LU, PA, KP, IN, PI or AL for all
	ORG2	2	
	ORG3	2	
	ORG4	2	
	ORG5	2	
	ORG6	2	
	ORG7	2	
	ORG8	2	
Kidney Side Code	KSIDE	1	Kidney only - R, L, B
Weight	WGT	3	Not Required for Kidney
Weight Unit	WGTUNIT	1	K, L Not Required for Kidney
Height	HGT	2	Required only for Lung
Height Unit	HGTUNIT	1	C, I Required only for Lung
Is There Time for a Cross Match	XMATCH	1	Y, N Required for Liver, Heart, Heart/Lung, and Lung
Left Bronchus	LBRONCHUS	2	Lung donors - in millimeters Optional
Right Bronchus	RBRONCHUS	2	Optional
Transverse Chest	TRCHEST	2	Heart/Lung, and Lung - in cm Optional
Vertical Chest	VTCHST	2	Heart/Lung, and Lung - in cm Optional
Zip	DZIP	5	Used for distance calculations. Display warning if left blank.
Variance variable	DLOCAL		
	L1	7	Local input variance
	RUN	2	Run number 01-35
	SEOPF	1	S - SEOPF, H - Highgrade, or blank if Universal
Date/Time stamp	STAMP		Generated - not entered by the user
	DDAY	2	
	D1	1	
	DMON	3	
	D2	1	
	DYEAR	2	
	SPACE	1	
	DHOUR	2	
	COLON1	1	
	DMIN	2	
	COLON2	1	
	DSEC	2	
Tray	TRAY	1	Y or N Used for KI, PA, KI/PA
Donor Provider Number	DPROVNUM	6	Lookup table required only for Tennessee
Previous Gastrointestinal Disease	PVGASTRO	1	Intestine donors
Hepatitis Positive	HCV+	1	+,- Liver, Pancreas, Kidney/Pancreas, Kidney, Intestines, Pancreas/Intestines
Space filler	FILR	6	

Appendix

Match Run Input Variances

NCNC - Carolina Organ Procurement Agency

```
If
    Center = NCNC
Then
    prompt user to enter actual donor center code
    set 1st 4 char of DLOCAL = actual donor center code
EndIf
```

NJTO - New Jersey Tissue & Organ Share

```
If
    Center = NJTO
Then
    prompt user to enter assigned transplant center code
    set 1st 4 char of DLOCAL = assigned transplant center code
EndIf
```

TXGC - Gulf Coast Organ Procurement Agency

```
If
    Center = TXGC
Then
    prompt user to enter region letter
        A    Houston
        B    Ft Worth
        C    Lubbock
    set 1st char of DLOCAL = region letter
EndIf
```

MWOB - Midwest Organ Bank

```
If
    Center = MWOB and Kidney Match is requested and Blood Group
    = A, A1 or A2
Then
    prompt user to enter A donor ABO subgroup
    set 1st char of DLOCAL = ABO subgroup
EndIf
```

TXSA - South Texas Organ Bank

```
If
    Center = TXGC
```

Then
 prompt user to enter region letter
 A San Antonio
 B Austin
 C OPO Wide
 set 1st char of DLOCAL = region letter
EndIf

LAOP - Louisiana Organ Procurement Agency

If
 Center = LAOP and Kidney Match is requested
Then
 prompt user to specify if import donor
 set 1st char of DLOCAL = import donor answer (Y or N)
EndIf

OKxx - All Oklahoma Centers

If
 Center = OKxx
Then
 prompt user to enter region letter
 A Oklahoma City
 B Tulsa
 set 1st char of DLOCAL = region letter
EndIf

TXSB - Southwest Organ Bank

If
 Center = TXSB
Then
 prompt user to enter region letter
 A Dallas
 B El Paso
 C Galveston
 D Tyler
 set 1st char of DLOCAL = region letter
EndIf

IAOP - Iowa Statewide OPO

If
 Center = IAOP

* It is not clear how DLOCAL gets set here

NEOB - New England Organ Bank

If

Center = NEOB and Kidney Match is requested

* It is not clear how DLOCAL gets set here

VAXx - Virginia Centers

If

Center = VATB

Then

prompt user to enter actual donor center code

set char 2-5 of DLOCAL = actual donor center code

Else

actual donor center code = center code (i.e. VAXx)

EndIf

If

actual donor center code = VAMC or VAMV or VAHD

Then

set 1st char of DLOCAL = 1

ElseIf

actual donor center code = VANG or VAKD

Then

set 1st char of DLOCAL = 2

EndIf

set char 2-5 of DLOCAL = actual donor center code

OC - Organ Center

If

Center = OCxx

Then

prompt user to enter actual Canadian donor center

* validate actual Canadian donor center

set 1st 4 char of DLOCAL = actual Canadian donor center

EndIf

* It is not clear what list or table is being used to validate the Canadian donor center.

Appendix

Center Data and Center Name File Conflicts

Center Code Conflicts

Center Code	Exists Only In . . .
ARBM	CENTNAMES.DAT
ARUC	CENTERS.DAT
AZHI	CENTNAMES.DAT
AZPH	CENTERS.DAT
CAG	CENTNAMES.DAT
CASR	CENTNAMES.DAT
DIAG	CENTERS.DAT
FLTV	CENTERS.DAT
GAEX	CENTERS.DAT
INVI	CENTERS.DAT
KSWV	CENTNAMES.DAT
KYKY	CENTERS.DAT
MDSG	CENTNAMES.DAT
METR	CENTERS.DAT
MIAA	CENTERS.DAT
MNMG	CENTERS.DAT
MOKV	CENTNAMES.DAT
MONH	CENTNAMES.DAT
MORE	CENTERS.DAT
MOTS	CENTERS.DAT
MWWL	CENTERS.DAT
NJSN	CENTERS.DAT
OC01	CENTERS.DAT
OC02	CENTERS.DAT
OC03	CENTERS.DAT
OC04	CENTERS.DAT
OC05	CENTERS.DAT
OC06	CENTERS.DAT
OC07	CENTERS.DAT
OC08	CENTERS.DAT
OC09	CENTERS.DAT
OC10	CENTERS.DAT
OC11	CENTERS.DAT
OC12	CENTERS.DAT
OC13	CENTERS.DAT
OC14	CENTERS.DAT
OC15	CENTERS.DAT
OKMH	CENTERS.DAT
OKSF	CENTNAMES.DAT
PAUF	CENTERS.DAT
PRUA	CENTERS.DAT
SDMK	CENTNAMES.DAT
TESQ	CENTERS.DAT
TNLB	CENTNAMES.DAT
TNTN	CENTERS.DAT
TOFA	CENTERS.DAT
TXBA	CENTNAMES.DAT
UTLS	CENTERS.DAT
VARM	CENTNAMES.DAT
WIMC	CENTERS.DAT
WIMM	CENTNAMES.DAT

Center Name File

Center Name File

ALBP	Baptist Medical Center	0	0	0	6 793KJ
ALOB	Alabama Organ Bank				
ALUA	Univ of Alabama Medical Center	0	0	0	6 793KJ
ARBH	Arkansas Baptist Medical Ctr.	3	10	92	31092KJ
ARBM	Baptist Medical Center	2	21	89	22189JA
ARCH	Arkansas Children's Hospital	0	0	0	31092KJ
AROR	Arkansas Organ Proc Agency	3	2	89	3 289JA
ARUA	U of Arkansas Medical Center	0	0	0	31092KJ
AZGC	GENETRIX	3	14	90	31490JA
AZGS	Good Samaritan Regional Med.	0	0	0	6 793KJ
AZHH	Healthwest Regional Med Cntr	9	7	88	6 793KJ
AZHI	Arizona Heart Institute	7	7	88	7 788JA
AZOB	Arizona Organ & Tissue Bank 1	0	3	88	52793KJ
AZSJ	St Joseph's Hospital, Phoenix	7	7	88	7 788JA
AZTV	V A Med. Ctr., Tuscon	0	0	0	41288OO
AZUA	University Medical Center	0	0	0	6 793KJ
CABE	St. Bernardine Medical Center	5	27	93	52793KJ
CABH	Alta Bates-Herrick, East Bay CA	2	8	88	2 888JA
CACL	Children's Hosp., Los Angeles	5	27	93	52793KJ
CACS	Cedars Sinai Medical Center	5	12	89	51289JA
CADN	California Tx Donor Network	5	27	93	52793KJ
CAEM	Eisenhower Memorial Hospital	5	27	93	52793KJ
CAG	Golden State OPA	1	2	91	52793KJ
CAGH	Green Hospital of Scripps Inst	7	13	90	71390JA
CAGS	Golden State Transplant Serv	5	27	93	52793KJ
CAIM	U.C.I. Medical Center	5	27	93	52793KJ
CALA	UCLA Medical Center, Harbor	6	7	93	6 793KJ
CALB	St. Mary Medical Center	6	7	93	6 793KJ
CALL	Loma Linda University Medical	0	0	0	52793KJ
CAMH	Santa Rosa Memorial Hospital				
CAOP	Southern California OPPC	1	20	88	12088JA
CAOT	San Diego Organ and Tissue	7	7	89	7 789JA
CAPM	Pacific Medical Center	0	0	0	52793KJ
CARZ	Hoag Memorial, Newport Bch, CA	1	25	90	12590JS
CASB	San Bernardino County Medical	5	27	93	52793KJ
CASC	Univ of Southern CA Medical	5	27	93	52793KJ
CASD	Univ of CA, San Diego, Med Ctr	0	0	0	52793KJ
CASF	Univ of CA, San Francisco	0	0	0	52793KJ
CASG	Sutter Memorial Hospital	6	7	93	6 793KJ
CASH	Sharpe Memorial Hosp.				
CASJ	Saint Joseph Hospital	6	7	93	6 793KJ
CASM	U. of California, Davis				
CASR	Santa Rosa Memorial Hospital 1	0	14	87	101487JA
CASU	Stanford University	2	19	88	21988JA
CASV	St. Vincent Medical Center	0	0	0	6 793KJ
CAUC	UCLA Medical Center	6	7	93	6 793KJ
CAUH	USC University Hospital	6	7	93	6 793KJ
CAWM	Western Medical Center	6	7	93	6 793KJ
CNHF	Victoria Gen. Hosp, Nova Scotia				
CNUA	U. of Alberta, Edmonton				
CNVG	Vancouver General Hosp.				
CNWM	Health Science Ctr., Manatoba				

Center Name File

COCH	Children's Hospital of Colo	4	25	90	42590JA
COIA	Immunological Assoc. of Denver				121290pw
COMH	Memorial Hospital	5	27	93	52793KJ
COPM	Porter Memorial Hospital	0	0	0	52793KJ
CORS	Colorado Organ Recovery System	3	29	88	52793KJ
COSL	Saint Lukes Hospital	0	0	0	52793KJ
COUC	University Hospital	0	0	0	52793KJ
CTHH	Hartford Hospital	0	0	0	52793KJ
CTYN	Yale Univ., New Haven Hosp.				
DCCH	Children's Hospital, National	0	0	0	6 793KJ
DCGU	Georgetown Univ. Med. Ctr.				
DCGW	George Washington U. Med. Ctr.				
DCHU	Howard University Hospital	0	0	0	52793KJ
DCTC	Washington Regional Tx Consort	2	10	88	52793KJ
DCWH	Washington Hospital Center	0	0	0	6 793KJ
DCWR	Walter Reed Army Med. Ctr.				
DEAI	Alfred I. Dupont Institute	5	27	93	52793KJ
FLAC	All Children's Hospital	5	27	93	52793KJ
FLBG	Broward General Hosp.				
FLDB	Halifax Hosp.				
FLFH	Florida Hosp., Orlando				
FLFL	Gainesville/Jax Joint List	8	25	89	82589JA
FLFM	Florida Hosp.				
FLFR	Southwest FL Regional Medical	8	29	90	52793KJ
FLJM	Jackson Memorial Hospital	0	0	0	6 793KJ
FLJT	Methodist Medical Center	3	29	89	52793KJ
FLMP	University of Miami OPO	5	27	93	52793KJ
FLMV	Miami VA Med. Ctr.				
FLOM	Orange Memorial Hosp.				
FLSF	U. of South Florida				
FLSW	Lifelink of Southwest Florida	5	27	93	52793KJ
FLTG	Tampa General Hosp.				
FLTO	Tallahassee Mem. Reg. Med. Ctr				
FLUF	U of FL Medical Center, Shands	0	0	0	52793KJ
GAEH	Egelston Children's Hospital	0	0	0	52793KJ
GAEM	Emory University Hospital	0	0	0	52793KJ
GAEU	Emory Univ. Hosp.				
GAGM	Grady Memorial				
GALL	Life Link of Georgia	2	10	88	52793KJ
GAMC	Med. College of Georgia				
GAPH	Piedmont Hospital	6	7	93	6 793KJ
GASJ	St Joseph's of Atlanta				
GAUH	University Hospital	6	7	93	6 793KJ
HIOP	Organ Donor Center of Hawaii	5	27	93	52793KJ
HISF	St. Francis Medical Center	0	0	0	6 793KJ
HOPE	HOPE Foothills Hosp.				
IAIM	Iowa Methodist Medical Center 1	1	24	87	52793KJ
IAIV	Iowa City V A Med. Ctr.				
IAMH	Mercy Hospital Medical Center	0	0	0	52793KJ
IAOP	Iowa Statewide OPO	9	25	89	52793KJ
ILCM	Children's Memorial Hosp.				
ILCR	Chicago Reg. Org. & Tissue Bnk	0	0	0	52793KJ

Center Name File

ILED	Edgewater Hosp.				
ILEH	Evanston Hospital 1	2	18	87	52793KJ
ILEN	Evanston Hosp.				
ILIP	Regionl Organ Bank of Illinois1	2	21	87	52793KJ
ILLU	Loyola University	0	0	0	6 793KJ
ILLV	Lakeside V A Med. Ctr.				
ILMM	Memorial Medical Center	0	0	0	6 793KJ
ILMN					
ILNM	Northwestern Memorial Hosp.				
ILPL	Rush Presb. St. Luke's Med. Ct				
ILSF	St. Francis Medical Center	0	0	0	6 793KJ
ILSM	St. Margaret Hosp.				
ILUC	University of Chicago Med. Ct				
ILUI	U. of Illinois Med. Ctr.				
ILVA	Hines VA	8	31	89	52793KJ
INCI	Central Indiana Regional Blood	5	27	93	52793KJ
INDV	Lakeview Hospital, Danville	4	12	88	52793KJ
INEV	St Mary's Hospital, Evanston	0	0	0	52793KJ
INFW	Lutheran Hospital, Fort Wayne	0	0	0	52793KJ
INHA	St Margaret's Hammond	0	0	0	52793KJ
INIM	Methodist Hospital of Indiana	0	0	0	52793KJ
INIU	Indiana Univ. Med. Ctr.				
INIV	Indianapolis V A Hosp.				
INLA	St Elizabeth's Lafayette	0	0	0	52793KJ
INLF	Lutheran Hospital	0	0	0	6 793KJ
INLH	Lutheran Hospital of Ft. Wayne	0	0	0	52793KJ
INMU	Ball Memorial Muncie	0	0	0	52793KJ
INOP	Indiana Organ Procurement Org 1	2	23	87	52793KJ
INSB	St. Joseph Hospital	0	0	0	6 793KJ
INSV	St. Vincent Hospital & Health	0	0	0	6 793KJ
INTE	Tri-State Renal Disease Ctr.				
INVA	VA Hospital Indianapolis	0	0	0	52793KJ
KSFT	St. Francis Hosp., Topeka				
KSFV	St. Francis Hosp., Wichita				
KSUK	Univ of Kansas Medical Center	0	0	0	6 793KJ
KSWV	VA Med. Ctr.,Wichita				
KYHH	Humana Hospital, Audobon	5	27	93	52793KJ
KYJH	Jewish Hosp.				
KYKC	Kosair Children's Hospital	6	7	93	6 793KJ
KYUK	U. of Kentucky Med. Ctr.				
KYUL	U. of Louisville OPA				
KYWK	OPA of Western Kentucky				
LANO	Louisiana State Med. Ctr.				
LAOF	Ochsner Foundation Hospital	0	0	0	52793KJ
LAOP	Louisiana Organ Procrmnt Agncy	3	17	88	52793KJ
LASB	Southern Baptist Hospital				
LASM	Schumpert Medical Center	0	0	0	52793KJ
LASU	Louisiana State Univ. Med. Ctr				
LATU	Tulane Univeristy Med. Ctr.				
LAWK	Willis-Knighton Medical Center	5	27	93	52793KJ
MABI	Beth Israel Hospital	0	0	0	52793KJ
MABS	Baystate Medical Center	5	27	93	52793KJ

Center Name File

MABU	Boston University Medical Cntr	0	0	0	6 793KJ
MABV	Boston V A Medical Center	0	0	0	6 793KJ
MACH	Children's Hospital Med. Cntr	0	0	0	6 793KJ
MAHS	Harvard Unit-NE Deaconess Hosp				
MALC	Lahey Clinic Medical Center	0	0	0	52793KJ
MAMG	Massachusetts General Hospital	0	0	0	6 793KJ
MANM	New England Medical Center	0	0	0	6 793KJ
MAPB	Brigham & Women's Hospital	0	0	0	6 793KJ
MAUM	Univ of Massachusetts Med Schl	0	0	0	6 793KJ
MDBC	Francis Scott Key Medical Cntr	0	0	0	6 793KJ
MDJH	Johns Hopkins Hospital	0	0	0	6 793KJ
MDPC	Maryland OPO 1	1	12	90	52793KJ
MDSG	Shady Grove Adventist Hospital	5	27	93	52793KJ
MDUM	Univ of Maryland Hospital	0	0	0	6 793KJ
MEMC	Maine Medical Center	0	0	0	52793KJ
MIBH	William Beaumont Hospital	0	0	0	52793KJ
MICH	Children's Hospital of Michign	0	0	0	52793KJ
MIHF	Henry Ford Hospital	0	0	0	52793KJ
MIHH	Harper Hospital	5	27	93	52793KJ
MIHM	Hurley Medical Center	0	0	0	52793KJ
MIKZ	Borgess Medical Center	0	0	0	52793KJ
MIMC	Grace Hospital	0	0	0	6 793KJ
MIMS					
MIOP	Organ Procurmnt Agency of MI	5	27	93	52793KJ
MISH	Mich. State U. Sparrow Hosp.				
MISJ	St John's Hospital and Medical	7	2	90	52793KJ
MISM	Mich. State U. St. Mary's Hosp				
MITS	Michigan TX Society				
MIUM	Univ. of Michigan Medical Cntr	0	0	0	6 793KJ
MIVA	Ann Arbor V A Med. Ctr.				
MIWS	Wayne State Univ. Hutzel Hosp.				
MNAN	Abbott North Western				
MNHC	Hennepin County General Hosp.				
MNMC	Mayo Clinic				
MNMV	Minneapolis V A Medical Center	0	0	0	6 793KJ
MNOP	UPPER MIDWEST OPO	6	2	88	6 288JA
MNSM	St Mary's Hospital	5	27	93	52793KJ
MNTL	Univ Minn Tissue Typing Lab 1	2	29	88	6 793KJ
MNUM	Univ of Minnesota Medical Cntr	0	0	0	6 793KJ
MOBH	Barnes Hospital	0	0	0	6 793KJ
MOCG	Cardinal Glennon Children's Hs	5	27	93	52793KJ
MOCH	St Louis Children's Hospital	0	0	0	52793KJ
MOCM	The Children's Mercy Hospital	0	0	0	52793KJ
MODU	De Paul Health Center 1	2	10	87	121087JA
MOJH	Jewish Hosp.				
MOKV	Kansas City V A Hosp.				
MOLH	St. Luke's Hospital of Kansas	0	0	0	6 793KJ
MOMA	Mid-America Transplant Assoctn	3	24	88	52793KJ
MOMM	Menorah Medical Center	1	6	88	1 688JA
MONH	Northland Comm. Dialysis Ctr.				
MORH	Research Medical Center	0	0	0	6 793KJ
MOSL	St. Louis Univ. Medical Center	0	0	0	6 793KJ

Center Name File

MOUM	U. of Missouri Med. Ctr.				
MSUM	U. of Mississippi Med. Ctr.				
MWOB	Midwest Organ Bank				
NCBG	Bowman Gray School of Medicine				
NCBH	North Carolina Baptist Hosp.				
NCCM	Charlotte Memorial Hospital	0	0	0	6 793KJ
NCCP	Carolina O P A				
NCDU	Duke University Medical Center	0	0	0	6 793KJ
NCDV	Durham V A Medical Center	0	0	0	6 793KJ
NCEC	East Carolina University	0	0	0	6 793KJ
NCMH	North Carolina Memorial Hosp.				
NCNC	Carolina Organ Procurement Agy	6	29	88	62988JA
NCRC	Charlotte Red Cross	3	25	88	32588JA
NDDH	Dakota Hospital North Dakota	6	8	89	41790JS
NDMC	Medcenter One Hospital 1	0	14	88	6 793KJ
NDSL	North Dakota St Luke's	4	17	90	41790JS
NDTB	N. Dakota Tx Svc Bismark Clini	1	19	90	11990JS
NDTC	N. Dakota Tx Svc Bismark Hosp	1	19	90	11990JS
NDTS	Transplnt Services of Fargo 1	0	18	89	101889JA
NEBM	Bryan Memorial Hospital	6	7	93	6 793KJ
NECM	Bishop Clarkson Memorial Hospl	6	7	93	6 793kj
NEOB	New England Organ Bank				
NEOR	Nebraska Organ Retrieval Sys.				
NEOX	New England Organ Bank OTO	0	0	0	41288CC
NESJ	Saint Joseph Hospital	6	7	93	6 793kj
NEUN	University of Nebraska Medical	6	7	93	6 793kj
NHDH	Mary Hitchcock Memorial Hosp.	6	7	93	6 793kj
NJBI	Beth Israel Medical Center	0	0	0	6 793kj
NJLL	Our Lady of Lourdes Med. Ctr.	0	0	0	6 793kj
NJSB	St. Barnabas Medical Center	0	0	0	6 793kj
NJTL	New Jersey Histo Lab 1	2	12	88	121288JA
NJTO	New Jersey Tissu & Organ Share	4	10	90	41090JA
NJUH	University Hospital	2	13	89	21389JA
NMAQ	U. of New Mexico				
NMOP	New Mexico Donor Program	6	7	93	6 793kj
NMPH	Presbyterian Hospital	0	0	0	6 793kj
NORS	Nebraska Organ Retrieval Svs	4	12	88	41288JS
NVHH	Humana Hospital Las Vegas	7	3	90	7 390JA
NVLV	Nevada Donor Refer System	4	11	88	41188JA
NVUM	So Nevada Medical Center	2	28	90	22890JS
NYAM	Albany Medical Center	0	0	0	6 793kj
NYAP	Albany Organ Proc Agency 1	2	12	89	121289JA
NYBC	Children's Hospital of Buffalo	6	7	93	6 793kj
NYBU	Buffalo Gen. Hosp. OPA of W.NY				
NYCL	Columbia Presb Tissue Typ. Lab1	2	20	89	122089JA
NYCO	NY Center for Liver Txplant	7	20	90	72090JA
NYCP	Columbia Presbyterian Hospital	0	0	0	6 793kj
NYDP	New York Gift of Life 1	1	13	87	111387JA
NYDS	Downstate Medical Center	0	0	0	6 793kj
NYEC	Erie County Medical Center	6	7	93	6 793kj
NYFL	Strong Memorial Hospital	6	7	93	6 793kj
NYIL	Rogosin Tissue Lab 1	0	26	89	102689JA

Center Name File

NYMA	Montefiore Hospital Med. Cntr	0	0	0	6 793kj
NYMH	New York, Mt Sinai	6	28	89	62889JA
NYMS	Mt. Sinai Medical Center	0	0	0	6 793kj
NYNY	New York Hospital	0	0	0	6 793kj
NYRT	New York Regional Transplant 1	1	2	89	11 289JA
NYSB	S U N Y at Stony Brook				
NYSL	St. Luke's Hospital	0	0	0	6 793kj
NYSM	Stong Memorial Hosp.				
NYUC	New York University 1	1	1	88	11 188JA
NYUM	S U N Y Upstate Med. Ctr.				
NYWC	Westchester Medical Center NY	7	18	89	71889JA
NYWN	O P A of Western New York				
OHAC	Akron City Hospital	0	0	0	6 793kj
OHCA	Akron Children's Med Center	0	0	0	5 488JA
OHCC	Cleveland Clinic				
OHCD	Canton Dialysis Center	6	8	88	6 888JA
OHCH	Children's Hospital	0	0	0	6 793kj
OHCM	Children's Hospital Med. Cntr	6	7	93	6 793kj
OHCO	Med. College of Ohio				
OHCV	Cleveland V A Medical Center	0	0	0	6 793kj
OHCW	Case W. Reserve Univ. Med. Ctr				
OHDC	Central Ohio Dialysis Ctr.				
OHDN	Doctor's North Dialysis	0	0	0	41288CC
OHLB	Life Banc of Ohio 1	0	26	87	102687JS
OHLC	Life Connection of Ohio	3	8	90	3 890JA
OHLI	Lima Dialysis Center	0	0	0	41288CC
OHLM	Lima Memorial Hospital	0	0	0	6 793kj
OHLP	Lifeline of Ohio 1	0	20	87	102087JA
OHMC	Mt. Carmel Hospital	0	0	0	6 793kj
OHMG	Metro General Hosp.				
OHMI					
OHMN	Mansville Dialysis Center	0	0	0	41288CC
OHMS	Mt. Sinai Hospital	0	0	0	6 793kj
OHMV	Miami Valley Hospital	0	0	0	6 793kj
OHOC	Organ Solid ORgan Consortia 1	1	16	89	111689JA
OHOR					
OHOU	Ohio State University Hospital	0	0	0	6 793kj
OHPH					
OHPM	Portsmouth Dialysis	0	0	0	41288CC
OHRH	Riverside Hospital Columbus	0	0	0	41288CC
OHSE	St Elizabeth's Medical Center	9	27	88	92788JA
OHSP	Springfield Dialysis	0	0	0	41288CC
OHSV	St. Vincent's Hosp. & Med. Ctr				
OHTC	The Christ Hospital	6	7	93	6 793kj
OHTH					
OHTL					
OHUC	Univ of Cincinnati Med. Cntr.	0	0	0	6 793kj
OHUH	Cleveland University Hospitals	5	4	88	5 488JA
OHZA	Zanesville Dialysis Center	0	0	0	41288CC
OKBC	Baptist Medical Center of OK	0	0	0	6 793kj
OKCM	Children's Memorial				
OKHM	Hillcrest Medical Center	0	0	0	6 793kj

Center Name File

OKMD	Oklahoma Memorial Hospital	0	0	0	6 793kj
OKOP	Oklahoma Organ Sharing Network	3	3	89	3 389JA
OKOV	Oklahoma City VA Medical Centr	0	0	0	6 793kj
OKSA	St. Anthony's Hospital	0	0	0	6 793kj
OKSF	St. Francis Hospital	9	13	93	KJ
OKTH					
ORUO	U. of Oregon Health Sci. Ctr.				
PAAE	Albert Einstein Medical Center	0	0	0	6 793kj
PAAG	Allegheny General Pittsburgh 1	0	26	87	102687JA
PACH	Children's Hosp. of Pittsburgh	6	7	93	6 793kj
PACP	Children's of Philadelphia	9	28	88	92888JA
PADV	Delaware Valley Transplant	4	18	88	41888JA
PAGM	Geisinger Medical Center				
PAHE	Hershey Medical Center				
PAHM	Hahnemann Medical College				
PALV	Lehigh Valley Hospital	6	7	93	6 793kj
PAPT	University of Pittsburgh				
PASC	St Christopher's Hosp./Children				
PATF	Pittsburg Transplant Foundatn 1	0	23	87	102387JA
PATJ	Thomas Jefferson Univ. Hosp.				
PATU	Temple Univ. Hosp.				
PAUP	U. of Pennsylvania Hosp.				
PRSJ	Auxilio Mutto Hospital	0	0	0	6 793kj
PRVA	Puerto Rico VA	0	0	0	41288JS
ROPA	R OPA of Southern California				
SCDF	Doheny Foundation (SPEC CORNA)	0	0	0	41288JS
SCKC	Kellogg Clinic (SPEC CORNEA)	0	0	0	41288JS
SCMU	Med. College of South Carolina				
SCOP	South Carolina Organ Procurement1	0	21	87	102187JA
SCWC	Wisconsin (SPEC CORNEA)	0	0	0	41288JS
SDMK	McKenna Hospital	6	7	93	6 793kj
SEOP	Southeastern Organ Procurement				
TNBM	Baptist Memorial, Memphis	3	3	88	3 388JA
TNDC	Tennessee Donor Svcs Nashville	0	0	0	41288JS
TNDS	Tennessee Donor Services	6	2	88	6 288JA
TNEM	Erlanger Medical Center Tenn. 1	0	19	89	101989JA
TNET	East Tennessee ROPA	9	8	88	9 888JA
TNJC	Johnson City Medical Center	6	7	93	6 793kj
TNLB	Le Bonheur Children's Center	2	7	94	2 794KJ
TNMH	Methodist Hospital of Memphis	6	7	93	6 793kj
TNMS	Midsouth Transplant Foundation	1	3	91	1 391JA
TNNV	Nashville V A Med. Ctr.				
TNPV	Nashville Presbyterian	6	23	89	62389JA
TNST	St. Thomas Hospital				
TNUK	U. of Tenn. Med. Ctr., Knox.				
TNUT	U. of Tenn. Med. Ctr., Nash.				
TNVU	Vanderbilt Univ. Med. Ctr.				
TXAD	Breckinridge Hosp.				
TXAV	Audie Murphy VA Medical Center	0	0	0	6 793kj
TXBA	Brooke Army Medical Center	9	13	93	kj
TXBC	U. of Texas Health Science Ctr	0	0	0	6 793kj
TXBU	Baylor University Hospital 1	2	29	88	122988JA

Center Name File

TXCM	Children's Medical Center	0	0	0	6 793kj
TXCT	Seton Medical Center	6	7	93	6 793kj
TXDR					
TXEA	Hotl Dieu Hospital				
TXEP	SWOB at El Paso	2	26	90	22690JA
TXFW	Tarrant County Nephrology Ctr.				
TXGC	Gulf Coast OPA				
TXHD	Humana Hospital, San Antonio	0	0	0	41288JS
TXHH	Herman Hospital				
TXHI	Texas Heart Institute				
TXHS	Humana Hospital, San Antonio	1	25	90	12590JS
TXHT	Home Training,Statewide				
TXJL	Galveston Tissue Antigen Lab	8	30	89	83089JA
TXJS	John Sealy Hosp./Univ of Tex.				
TXKD	South Texas Kidney Disease Ctr				
TXLA	Laredo				
TXLG	Lubbock General, Texas	4	14	88	41488JA
TXLM	Methodist Hospital, Lubbock	7	2	90	7 290JA
TXMC	Methodist Central, Dallas	0	0	0	41288JS
TXMH	Methodist Hospital	0	0	0	6 793kj
TXPM	Parkland Memorial Hospital	0	0	0	6 793kj
TXSA	South Texas Organ Bank				
TXSB	Southwest Organ Bank	9	8	88	9 888JA
TXSH	Spohn Hospital	0	0	0	6 793kj
TXSM	Sierra Medical, El Paso	3	29	88	32988JA
TXSP	St. Paul Medical Center	0	0	0	6 793kj
TXSR	Santa Roas Hosp.				
TXST	South Texas Dialysis Center	0	0	0	6 793kj
TXSW	University Texas at Dallas 1	2	18	87	121887JA
TXTC	Texas Children's Hospital	6	7	93	6 793kj
TXTL	Univ Texas SW Medical Center	8	23	88	82388JA
TXTX	Baylor University Hospital	0	0	0	6 793kj
TXTY	Medical Center Hosp, Tyler	4	29	88	42988JA
TXUT					
TXVU	Vall Urology Clinic				
TXWA	WACO				
TXWH	Wilford Hall Med. Ctr. (USAF)				
UNOS	United Network for Organ Shari				
UTAH	UTMC&UTLD Cardiac TX Program				
UTLD	Latter Day Saints Hospital	0	0	0	6 793kj
UTMC	Intermount Org. Bank/U. of UT				
UTOP	Intermountain Organ Recovery 1	1	18	87	111887JA
UTPC	Primary Children's Medical Ctr	6	7	93	6 793kj
UTVA	VA Medical Center, Salt Lake	6	7	93	6 793kj
VAFH	Fairfax Hospital	0	0	0	6 793kj
VAFP	Fairfax Hospital Association 1	0	27	87	102787JA
VAHD	Henrico Doctors'	8	10	89	81089ja
VAKD	Children's Hosp Kings Daughter	8	10	89	81089ja
VALD	Leigh Memorial Hosp.				
VAMC	Med. College of Virginia				
VAMV	McQuire V A Medical Center	0	0	0	6 793kj
VANG	E. Va Med. Ctr./Norfolk Gen				

Center Name File

VAOP	Virginia Organ Procurement Agy	6	21	88	62188JA
VAPG	Petersburg General	0	0	0	41288JS
VARH	Riverside Hospital	0	0	0	6 793kj
VARM	Roanoke Memorial Hospital	6	7	93	6 793kj
VATB	Virginia Tissue Bank 1	0	20	87	102087JA
VAUV	U. of Virginia Medical Center				
VTMC	Med. Ctr. of Vermont				
WACH	Children's of Seattle	1	9	90	1 990JA
WANW	Northwest Medical Center	0	0	0	6 793kj
WASH	Sacred Heart Hosp Spokane Wa	0	0	0	4 188JS
WASM	Swedish Hospital Medical Cente	6	7	93	6 793kj
WAUW	University of Washington	1	9	90	1 990JA
WAVM	Virginia Mason Medical Center	6	7	93	6 793kj
WICH	Children's Hospital of Wiscons	6	7	93	6 793kj
WIMM	Milwaukee County Medical Compl	6	7	93	6 793kj
WIOP	Wisconsin Organ Procrmnt Orgnz	3	14	89	31489JA
WISE	Froedtert Memorial Luth. Hosp.				
WISL	St. Luke's Hosp. & Org.Network				
WIUW	Univ of Wisconsin Hospital	0	0	0	6 793kj
WVCA	Charleston Area Medical Center	3	14	88	31488JA
WVCC	WV Cross Roads Community Hosp.				
WVMS	Mountain State OPA 1	0	27	87	102787JA
WVWU	West Virginia University	0	0	0	6 793kj

XPEDITE

ORGAN INFORMATION SYSTEM

System Analysis & Design Project

Prepared by

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for

Dr. C. S. Ferguson, Ph.D.
CIS 5520

&

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United Network for Organ Sharing

April 24, 1995

ABSTRACT

CHARLES J. HUTSON. XPEDITE organ information system

Purpose. To research, analyze and present the rationale for the development of the Xpedite organ information system by the United Network for Organ Sharing (UNOS). Further, to explain the components and processes of the Xpedite system.

Method. The author interviewed Mr. David Klein, M.E.A., UNOS Director of Computer Services, and used personal insight of the system, gained through the author's development of a marketing plan for Xpedite during October and November, 1994. Additionally, the author is a member of the UNOS Patient Affairs Committee and has been an advocate for transplant patients since 1992.

Report Contents. This report includes the following; (1) Transplantation: A Brief History, (2) Current System, (3) Purpose Statement, (4) Scope of the Project, (5) The Xpedite System, (6) Xpedite Context Diagram, (7) Xpedite Figure 0 Data Flow Diagram, (8) Implications for Organ placement, (9) Xpedite Benefits Summary, (10) Considerations for Future Development, (11) Input/Output Documents with Descriptions, (12) P.I.E.C.E.S. Problem-Solving Framework, and (13) Appendices with Skytel Network Information, UNOS GST Framework and Input/Output Forms

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P R E F A C E

During the past two years the United Network for Organ Sharing (UNOS) has been working on a system to reduce the time interval between initial notification of a potential donor by a hospital, and the final placement of the organ for transplantation. The evolution of this system has resulted in the evaluation of several promising possibilities, only later to have these ideas fall victim to better alternatives. This has also been true of the process of naming this system. In the early development there was no name, then as the system gained shape it was named VITALINK. However, as the system approached the phase where marketing could begin, a trademark search was conducted and it was discovered the name was protected. A search for a new name ensued and in the interim the system was called the Organ Information System. Finally, an official and public name for the system was selected-- XPEDITE. This paper attempts to present the rationale used for determining the need for Xpedite, and to discuss the components and benefits of the system.

A C K N O W L E D G E M E N T S

As the author of this report I gratefully acknowledge the time, effort and contribution of David Klein, UNOS Director of Computer Services, for his assistance and advice. Prior to this report David and I worked together on the development of a marketing plan for Xpedite and recently completed work on a promotional brochure for Xpedite which informs and educates the transplant community of Xpedite's benefits.

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TRANSPLANTATION: A BRIEF HISTORY

In the early 1950's Dr. David Hume of Harvard University ushered in the era of transplantation, with the successful transplantation of renal organs in the thighs of patients. For more than a decade several different procedures and immunosuppression medications were tried with very limited success. Then in 1963 a series of drug therapies were developed that resulted in reports of one year survival rates of up to 85% in renal patients. In 1967 Dr. Christian Barnard performed the first successful heart transplant. In the early 1970's Dr. Roy Calne in England and Dr. Tom Starzl in the U.S. successfully began liver transplantation.¹ In addition to improvements in surgical procedures the two most significant developments in transplantation during this period were (1) the development of the highly successful immunosuppression medication, cyclosporine and (2) the development of a reliable solution for the preservation of organs at the University of Wisconsin (UW solution).

With all of these advances, the number of patients wanting transplants out-stripped the available donor supply. The federal government felt that the early methods of organ sharing should be formalized through legislation. In 1984, Congress passed the law creating the national Organ Procurement and Transplantation Network (OPTN). In 1986 the United Network for Organ Sharing (UNOS), a creation of the previous voluntary organ sharing system of the South East Organ Procurement Foundation (SEOPF), received a contract from the federal government to implement the OPTN system.² Since then, UNOS has continued to implement programs and systems to (1) successfully match available donor organs with the most suitable transplant candidate and (2) explore new and innovative ways to make the system more responsive to meet

¹ Michael G. Phillips, UNOS Organ Procurement, Preservation and Distribution in Transplantation (UNOS 1991)

² IBID., pg. 5

the needs of transplant candidates. Of major concern to UNOS, is the development of programs and systems that will close the gap between the number of organs needed and the number of organs available. This shortage alone results in the death of eight people each day.

UNOS' most recent innovation to solve this discrepancy is the Xpedite organ information system. The major benefits of Xpedite are (1) Xpedite will reduce the amount of time necessary to place available organs and (2) implementation of Xpedite will result in an increase in the number of usable organs. With Xpedite, notification of transplant center priorities for all organs (of a single donor) are simultaneously are transmitted to all transplant centers; thus widening the scope of organ offerings and thereby resulting in the opportunity for greater organ placement.

CURRENT SYSTEM

In 1993, there were 33,352 transplant candidate waiting on the UNOS list (up from 29,415 in 1992, a 13.4% increase).³ Further, in 1993 there were 18,168 transplants performed at 265 transplant centers.⁴ These centers receive organs from 67 organ procurement organizations (OPO), with each of the approximately 4,100 donors, donating up to seven major organ (heart, liver, pancreas, two lungs, and two kidneys). The focal point of the organ recovery process is the organ procurement coordinator, who must:

1. Provide complete management of the donor including all medical related processes,
2. Interface with the grieving donor family,
3. Complete a series of as many as seventeen different forms (copies of these forms are included in Appendix C) concerning donor characteristics, laboratory information and organ specific data,
4. Fax the forms to the UNOS organ center to be entered in the UNOS computer system so that a match run can be initiated,
5. Wait for match run results and then review results to understand the priorities of each potential transplant candidate,
6. Call each transplant center, one after the other, with a priority for **EACH** organ, and;

³ Annual report of the U.S. Scientific Registry of Transplant Recipients and the Organ Procurement and Transplantation Network (UNOS, 1994)

⁴ IBID., pg. ES-15

7. Explain verbally to transplant center officials, the donor information with sufficient specificity for the center to make a decision with regard to acceptance or rejection of the organ for their candidate.

If an organ is rejected by a transplant center, this process is repeated again and again until each organ is accepted. Valuable time, often hours, are lost and frequently placing multiple organs is impossible because of time constraints.

Some of the difficulties of this system are obvious, the most serious being the potential for miscommunication and time delays waiting for return calls between transplant centers and procurement coordinators. The stress on procurement coordinators results in increased risk of error in donor management. Other difficulties are less obvious such as misinformation being communicated to the transplant center resulting in acceptance of an organ and then later, once the surgeons arrive to remove the organ, a reassessment results in the receiving hospital declining the organ. This is an expensive and time consuming problem which often results in an otherwise usable organs not being placed due to deterioration of the organ. Another potential problem is that the coordinator recovers the organ and ships the it to the transplant center. The receiving transplant center rejects the organ because of the limited amount of information available at the time of acceptance, increasing expense and the potential for losing a life saving organ.

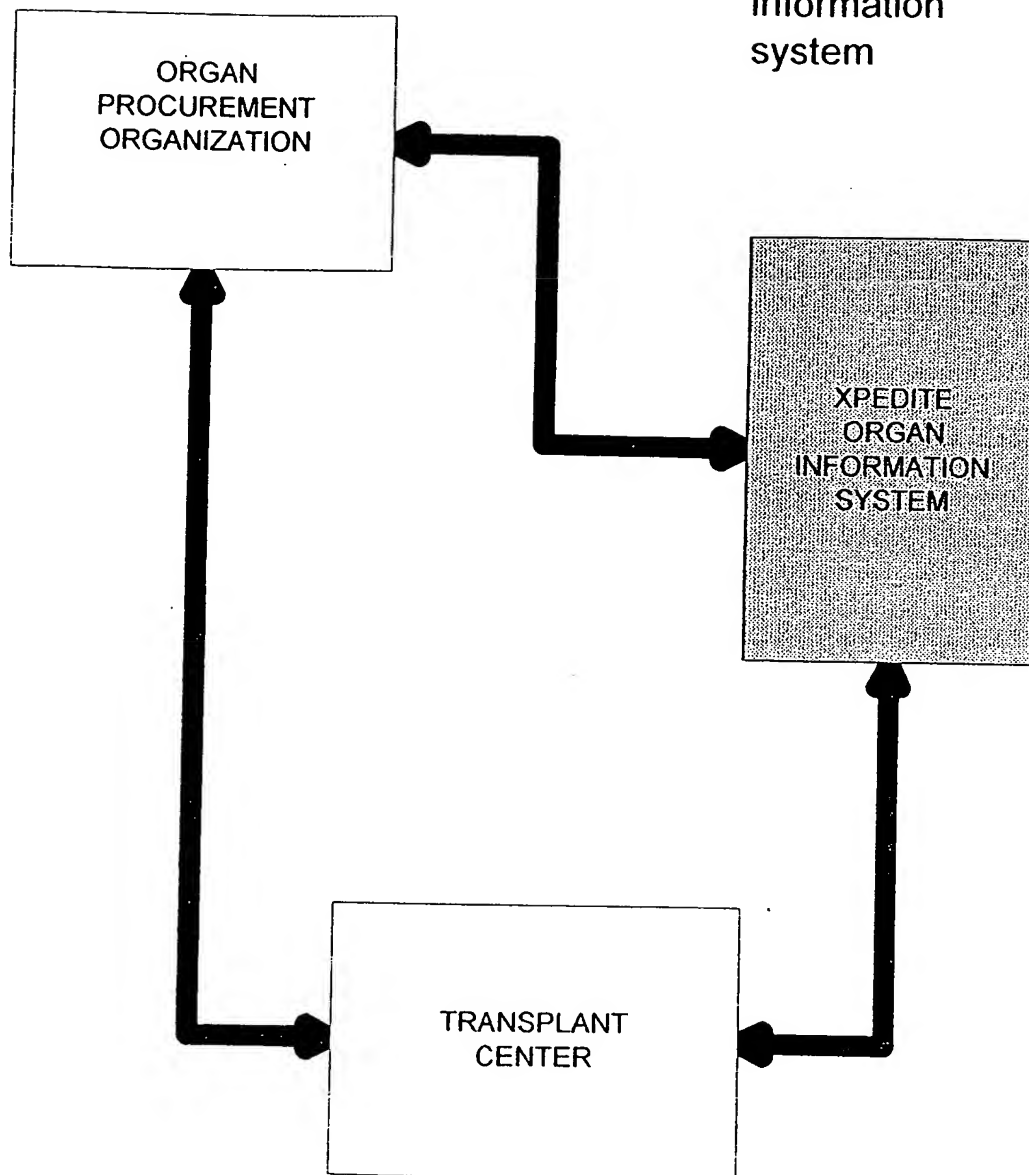
PURPOSE STATEMENT

The purpose of this project is to research, analyze and present the rational for development of a system that will reduce the time necessary to place human organs for transplantation and to explain the components and processes necessary to accomplish the project objectives.

SCOPE OF THE PROJECT

Due to the enormous complexities of organ recovery and placement process, it is necessary in the context of this analysis to limit the discussion to an overview perspective of the system. Such a

unos
xpedit
organ
information
system



context
diagram

sophisticated and revolutionary system does and will continue to require modifications to the system and procedures necessary for implementation. To this end, the system has been through Alpha and Beta testing at various Organ Procurement Organizations (OPO) in throughout the United States. Currently, final testing is underway at the UNOS Organ Center and some OPO's. Upon the successful completion of this testing, proper training materials will be prepared by UNOS. At that point marketing, installation, and full nationwide implementation will begin. However, for the purpose of this discussion the focus will be viewing the general principles and methods used in the deployment of this system.

THE XPEDITE SYSTEM

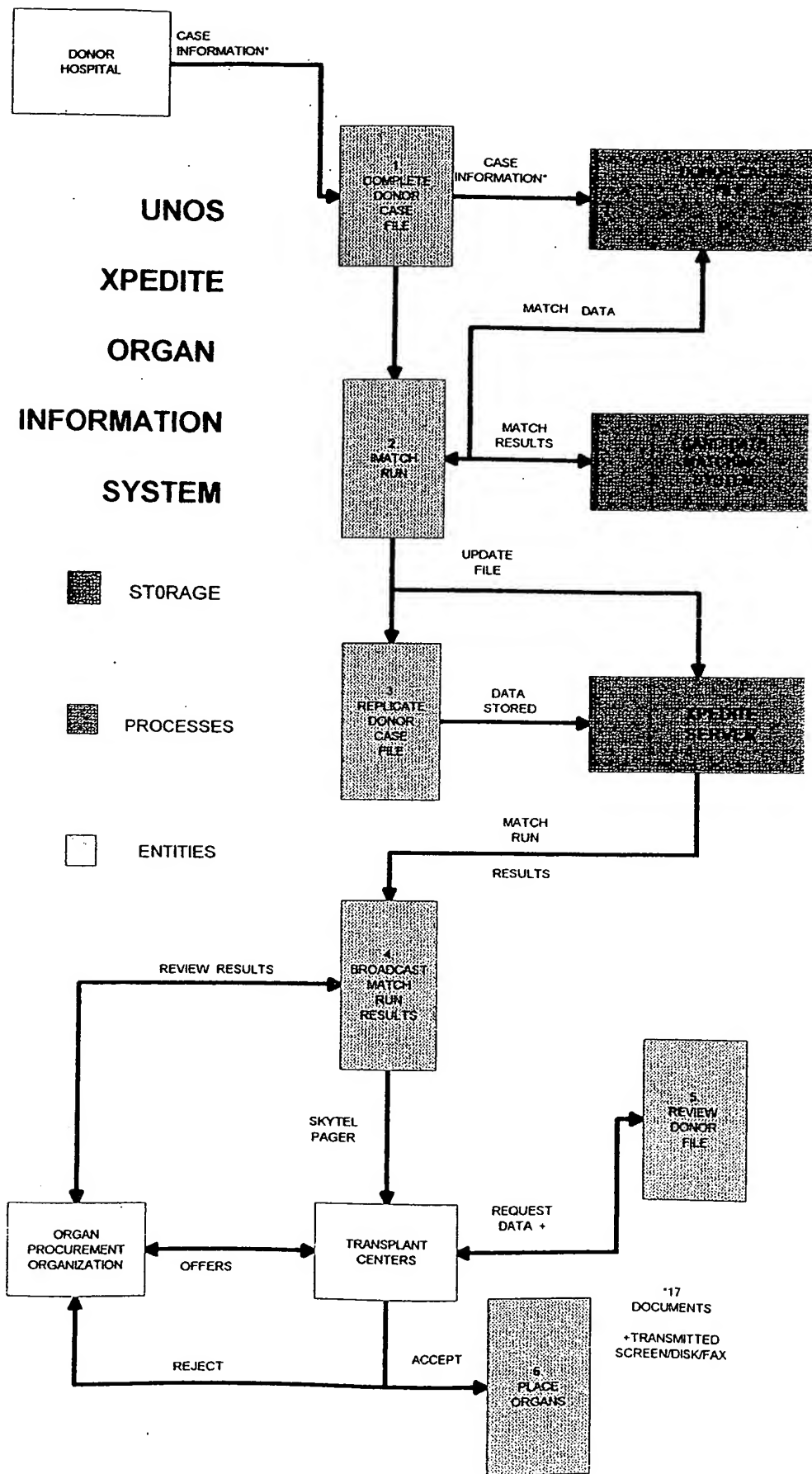
Xpedit is a system that combines the portability and capabilities of today's sophisticated notebook personal computers and Microsoft Windows compatible software to improve the process of decision making during the placement of human organs for transplantation. Each year more than 18,000 people, with life threatening end stage organ disease, rely on the success of this process to save their lives. With Xpedit, the procurement coordinator:

1. Collects donor data on a notebook PC. All seventeen forms (which prior to Xpedit were completed by hand) necessary for the completion of the organ placement process have been programmed into the PC as input/output screens (a complete discussion of these input/outputs are included on page 11) using Lotus Notes software.
2. Once sufficient data has been collected the coordinator, using the notebooks' modem, dials into the UNOS Organ Center and connects to the Xpedit server. The coordinator downloads the information and replicates the complete donor file onto the Xpedit server,
3. The coordinator initiates a Match Run,
4. Match Run results are simultaneously transmitted back to the coordinator and **ALL** transplant centers with priority are notified via a Skytel digital pager,
5. Transplant center professionals with Xpedit software can then dial-in to the Xpedit server and view the donor case file and/or download the file to their system (centers without Xpedit can still receive the donor file using the Xpedit Fax-back feature), and;
6. The coordinator calls the center for a decision on accepting or rejecting the organ. If the organ is accepted that is the end of the process, if rejected the coordinator continues to call centers, in order of priority, until the organ is accepted.

The Match Run is a key point in this process. The coordinator may chosen to initiate the match run to determine, for example, the first 25 centers for kidneys, first 15 for livers and so on for each organ. As the name implies, the information concerning the donor is matched with the list of more than 38,000 (1995 estimate) waiting transplant candidates to determine the prioritization of candidates to receive the donor organs. The criteria for this analysis and prioritization is very complex. Evaluation is based upon a balance of utility, justice and medical need. The needs of the local community are balanced against the belief that donor organs are a national resource. A point system has been implemented for ranking candidates for all solid organs except lungs. This point system includes evaluation based on severity of condition, degree of compatibility with the donor, distance between the donor and the candidate and length of time on the list. These and other evaluation criteria are included in the Match Run.

Upon completion of the Match Run, results are transmitted to the OPO's procurement coordinator (results include the candidate identification number, type of organ and the name of the transplant center with their priority and other related information) who reviews the results and begins contacting transplant centers to discuss the case and elicit a decision from the center to accept or reject the offer.

Xpedite broadcasts to each of these centers data on their priority. Each center's contact representative will be equipped with a Skytel digital pager (information concerning Skytel is included in Appendix A). Xpedite transmits a message that may include the donor's UNOS identification number, type of organ being offered, priority number and contact telephone number.



Armed with this information the transplant center surgeon or transplant coordinator can dial into the Xpedite system server at UNOS. If the transplant center has purchased the Xpedite system they can then use their system to review the donor data on-line or download the information to their system. In either case, this information is then evaluated by center officials and a decision can be made whether to accept or reject the organ, if it is offered, in advance.

The advantages of this system are that center personnel are making decisions based upon access to the entire donor file (not just what can be communicated by phone and fax as were previously done) and that the center can make advance decisions. If an offer is made, the center can quickly give the procurement coordinator a fully informed decision. If the decision is to accept the offer and transplant the organ, the organ recovery and transplant process can begin immediately. On the other hand, if the decision is to reject the offer, the coordinator can be quickly informed and move on to another inquiry.

Those centers who do not purchase the Xpedite system can still access the donor information by using the Xpedite fax-back system. With this component of the Xpedite system center personnel dial-in their request to the electronically answered system and the system immediately faxes the requested information back.

Xpedite will reduce the organ placement process by several hours and will result in the placement of more usable organs. For some organs there is a very short window of opportunity for placement and transplantation (4-6 hours for hearts and lungs), while others have more time (24-48 hours for kidneys and livers). It is imperative that the data collection and organ placement processes operate efficiently. With Xpedite the timeliness of these processes are improved.

IMPLICATIONS FOR ORGAN PLACEMENT

It is the author's belief that there are factors inherent in the existing system that often cause the more time sensitive organs to be placed last or not at all, in favor of organs with a longer time in which successful placement can result. The primary reasons for this are:

- (1) experience on the part of procurement coordinators that tells them that placement is a long and tedious process, therefore it is more efficient to spend the time placing the organs you can (liver and kidneys) than to chase placement of organs with shorter life cycles (heart and lungs) that you may not get placed anyway;
- (2) that this system was developed and perfected over the years by people whose primary interest was renal disease and it's treatment and therefore there is a natural predisposition toward kidney organ placement and;
- (3) that there are five to six times as many kidney patients awaiting transplantation as there are hearts and lungs, therefore there is a perception that the need for kidneys is greater than for other organs.

With Xpedite the hope is that improvement in this process will result in greater placement of all types of organs over a short period of time.

XPEDITE BENEFITS SUMMARY

The full implementation of the Xpedite system will result in many benefit to patients, procurement coordinators, transplant center professionals, UNOS staff and medical researchers in the field of transplantation. Following is a summary of these benefits:

1. Time Reduction - Xpedite compresses the process, enabling a candidate match for an organ in the least amount of time possible. The time saved, results in a direct increase in life saving organ placement.
2. Donor Family - Families who consent to donate their loved one's organs must wait hours until organs are recovered. Xpedite speeds the placement process, sparing families a lengthy and anxious wait before the body can be released for funeral arrangements.
3. Lower Medical Costs - Prior to organ recovery, donors are maintained in expensive critical care facilities during the placement process. Xpedite lessens the time donors spend in expensive facilities, thus reducing insurance and Medicare/Medicaid costs.
4. Higher Productivity/Less Stress - Xpedite allows procurement coordinators to concentrate on donor management by automating much of the placement process.

5. Medical Research - Xpedite will produce a rich research database that does not exist today. This database will be utilized to analyze and study the donor placement process, the donor population and may ultimately improve the national policies on organ allocation.

CONSIDERATIONS FOR FUTURE DEVELOPMENT

During the development of this report it became clear that the improvements Xpedite offers are many and varied. Further, as a result of the immediacy of this system, it would become possible for time sensitive data, such as an active donor case record, to become outdated very quickly. The impact of this prospect, is that during the decision making process the donor record at the transplant center does not contain an information base as current as the procurement coordinator's case file nor that on the Xpedite server. Therefore, it may be advisable upon wide spread implementation of the system to establish a procedure to instruct transplant centers to update their record at some pre-determined time interval as long as the case remains active. Possible long term solutions may be to include some method of time stamping all records with the date and time of last update. This would assure that all systems in the process have that most current data available.

Additional considerations for development might include further automation of the decision making process by eliminating the need for voice communication and completing the process with the Xpedite data network. Finally, as Xpedite gains wide acceptance the users of the system will uncover new and innovative ways to improve the system even further.

UNOS XPEDITE SYSTEM

INPUT/OUTPUT DOCUMENTS WITH DESCRIPTIONS

Following is a list of inputs and outputs for the UNOS Xpedite System with all related documents included in Appendix C. Each form in this appendix is separated with a numbered tab divider that corresponds to the item number shown below. This is an interactive system, as a result most input forms/screens are also output once data is included.

The current manual donor registration form is included for reference. However, in the new Xpedite system the data captured is divided into three separate groupings, based upon the usefulness of the groupings, Donor Data, Lab Data and Organ Specific Data.

INPUT ONLY

1. Intraoperative Management Form - provides data concerning the management of the donor during the organ recovery process and includes blood pressure, heart rate, medications dispensed with dosages and the time administered.
2. Match Run Input Form - includes that data required to identify the donor by name and UNOS identification number plus donor demographics and the type of organs to be matched. This form also allows the user to establish the maximum number of candidates the match run output will provide.

INPUT/OUTPUTS

Donor Data

3. Donor Registration Form - provides a compilation of data from several other form.
4. Medical/Social History - provides for a complete medical and social history of the donor including 34 specific questions addressing previous health concerns and lifestyle issues
5. Consent & Admission - provides data concerning the consent of Next of Kin for organ donation including the name, address, telephone number and relationship of the Next of Kin to the donor. Also included are the date and time of consent with a complete list of decisions for each organ
6. Case Information - provides data concerning the managerial responsibilities for the donor including OPO and coordinator information, donor hospital with

attending physician information, Medical Examiner case information (if required), and information concerning the reason/circumstances of brain death

7. Initial Physical Assessment - provides data concerning the original evaluation of the donor with specific evaluation of pulmonary, cardiovascular, integumentary, gastrointestinal, genitourinary and musculoskeletal systems

Lab Data

8. Medications - provides historical information concerning the donor's medication usage and medications given to the donor during the 24 hour period prior to cross clamp

9. Serology - provides specific blood study data on the donor including results of such tests as HIV etc.

10. Pulmonary Data - provides relevant pulmonary data of the donor with fields for interpretation and comments by appropriate personnel

11. Microbiology - provides result of several relevant laboratory studies of the donor including 24 hour, 48 hour and final results of the studies

12. Arterial Blood Gases - provides data indicating the results of relevant blood gas studies

13. Cardiac Data - provides data concerning relevant heart information including EKG results and drug name and dosages provided to the donor

14. CBC & Diff - provides data concerning the date time and results of additional blood studies from time of admission including red and white cell counts

15. Chemistry - provides data concerning complete chemistry panel for the donor from the time of admission

16. Hemodynamics/Temperature - provides composite data concerning the donors blood pressure, heart rate, temperature and other relevant information from the time of admission

17. Intake/Output - provides data concerning the volume of liquid and solid substances consumed by the donor and urine and non-urine discharge from the donor

Organ Specific

18. Lung Data - provides relevant data concerning the donor's lungs

- 19. Liver Data - provides relevant data concerning the donor's liver
- 20. Kidney Data - provides data concerning the renal organs of the donor
- 21. Heart Data - provides data relevant to recovery of the donor heart

OUTPUT ONLY

- 22. Match Run Output - provides information establishing the priority for acceptance or refusal of the organ being offered

INFORMATIONAL

- 23. Fax Memos - a series of fax cover memos indicating the data concerning the sender and recipient of the fax together with a checklist of documents from among the several above that are included with the fax

PIECES

PROBLEM-SOLVING FRAMEWORK AND CHECKLIST FOR THE UNOS XPEDITE SYSTEM

The PIECES Framework is utilized as a determinant of the efficacy of the new UNOS Xpedite automated organ recovery system when compared to the current manual organ recovery approach.

Performance improvement are examined based upon throughput and response time.

1. Throughput improvements are central to the success of the new system.

Currently, delays occur in disseminating collected donor information concerning each organ to the many transplant centers once priority is established for each organ. None of the donor data is maintained in any computer system. As a result, many times those organs that are most sensitive to deterioration (heart and lungs) cannot be utilized because of the long delays (potentially up to twenty-four hours) procurement coordinators experience in placing organs in greater demand (i.e. kidneys). With the new Xpedite System once donor information is collected via a laptop computer at the donor's bedside (currently done using the manual completion of paper forms), the coordinator transmits the information to the UNOS Matching system and all the transplant centers with priority candidates are notified electronically and simultaneously. Thus, necessary notifications that traditionally required several hours can now be completed in minutes. There are three components of this system that need to be examined from the standpoint of throughput:

A. Procurement Coordinator - The amount of time required by the procurement coordinator to reach a point where a match run is initiated will probably increase initially for those coordinators that are not computer software/hardware literate. Other coordinators may likewise see throughput decrease until they have gained some experience with the system. It is for this reason that UNOS will designate staff to provide a training assessment in prerequisite skills for coordinators. UNOS has also considered

pen-based input devices attached to the notebooks. To reduce the impact of lack of keyboard skills UNOS will provide training in utilization of Xpedite. These potential delays in the long run will reduce the time required by coordinators to initiate a Match Run. The additional throughput period will be from the time Match Run results are received until the last donor organ is removed from the donor hospital. This time period may be cut by 50% or more. At the same time the number of organs placed is likely to increase.

B. UNOS Organ Center - Throughput for the organ center will be cut to nearly zero due to the complete automation of the system and the elimination of staff to enter donor data into the computer, initiate the match run, and fax results to the procurement coordinator.

C. Transplant Center - The throughput time for transplant centers is likely to increase as they will now have access to more data upon which to make decisions on the acceptance of an organ offer. As center officials gain more experience in using the system throughput is likely to be comparable to that in the current system.

2. Similarly response time has been a time consuming process. Often transplant centers have had to make decisions with incomplete information, which has resulted in an organ being sent that the center was then unable to use for the intended candidate (because of incomplete information at the time of acceptance). With the new system decision makers at transplant centers will have more complete, accurate and readable Donor Registration forms from which to render a decision.

Information is the essence of the organ recovery process. The current manual system essentially requires all decisions to be made on the basis of faxed donor forms, which are most often incomplete, and verbal communications between the Procurement Coordinator and Transplant Center personnel. This information must then be communicated to other responsible decision makers at the center. The question is not, "Do miscommunications occur?" but in a system that is so critical to life, "Is there a better way to eliminate the possibility of miscommunication?". The answer is the new

system that places complete donor medical profiles directly in front of the decision makers.

When this information is completed (as a result the procurement coordinator entering the data in a notebook PC with the Xpedite software) the coordinator transmits this data via modem to the Xpedite server at the UNOS Organ Center. Transplant center officials with a Skytel pager are notified of their priority. If center personnel have an Xpedite system they then go on-line and review the donor data and/or download the data to the center's system. For those centers without Xpedite these centers can dial into the Xpedite server and use the fax-back system to receive copies of the data forms.

Economics or reduced costs is an additional benefit of the new system. Prior to organ recovery, donors are maintained in expensive critical care facilities during the placement process, which requires several hours and in some instances days. The new system reduces the time donors spend in expensive facilities which translates into lower costs. Additionally, by reducing staff time in the organ placement process costs are reduced.

Control and security is insured by allowing only authorized purchasers of Xpedite access to the system. Passwords may be required at the user and system levels and donors and candidates are identified only by UNOS registration identification numbers. Once documents have been entered into the system, modification of the data is strictly limited with alterations documented for further tracking. Field systems backup is available on all systems and procedures at UNOS for system backup assure the protection of the data.

Efficiency improvements are substantive in the Xpedite system. Reducing by several hours the amount of time required to place organs directly, translates into improved graft and patient survival. Further, the long term improvements in quality of life as a

result of lower ischemic (cold storage) time have been documented in several scientific studies.

Service improvements are easily recognizable for the Procurement staff, Transplant Center personnel, transplant candidates and UNOS. Procurement coordinators perform their duties under extreme pressure. The more time that can be spent on donor management, and the less on paperwork and outside communication, the greater the probability of improved donor management. Transplant Center personnel with more accurate, timely, and readable information are better positioned to make critical decisions. Transplant candidates benefit as a result of the increased probability that organs will be recovered and that the organ is "right " for the candidate. Additionally, UNOS benefits by offering a technology that once again demonstrates their leadership ability in the transplant community. Finally, Xpedite will provide UNOS with a body of information and a database that does not currently exist. This data may provide untold clues to understanding the donor population of the U.S. transplant program.



THE SKYTEL® UPDATE

VOLUME TWO, NUMBER THREE, 1994

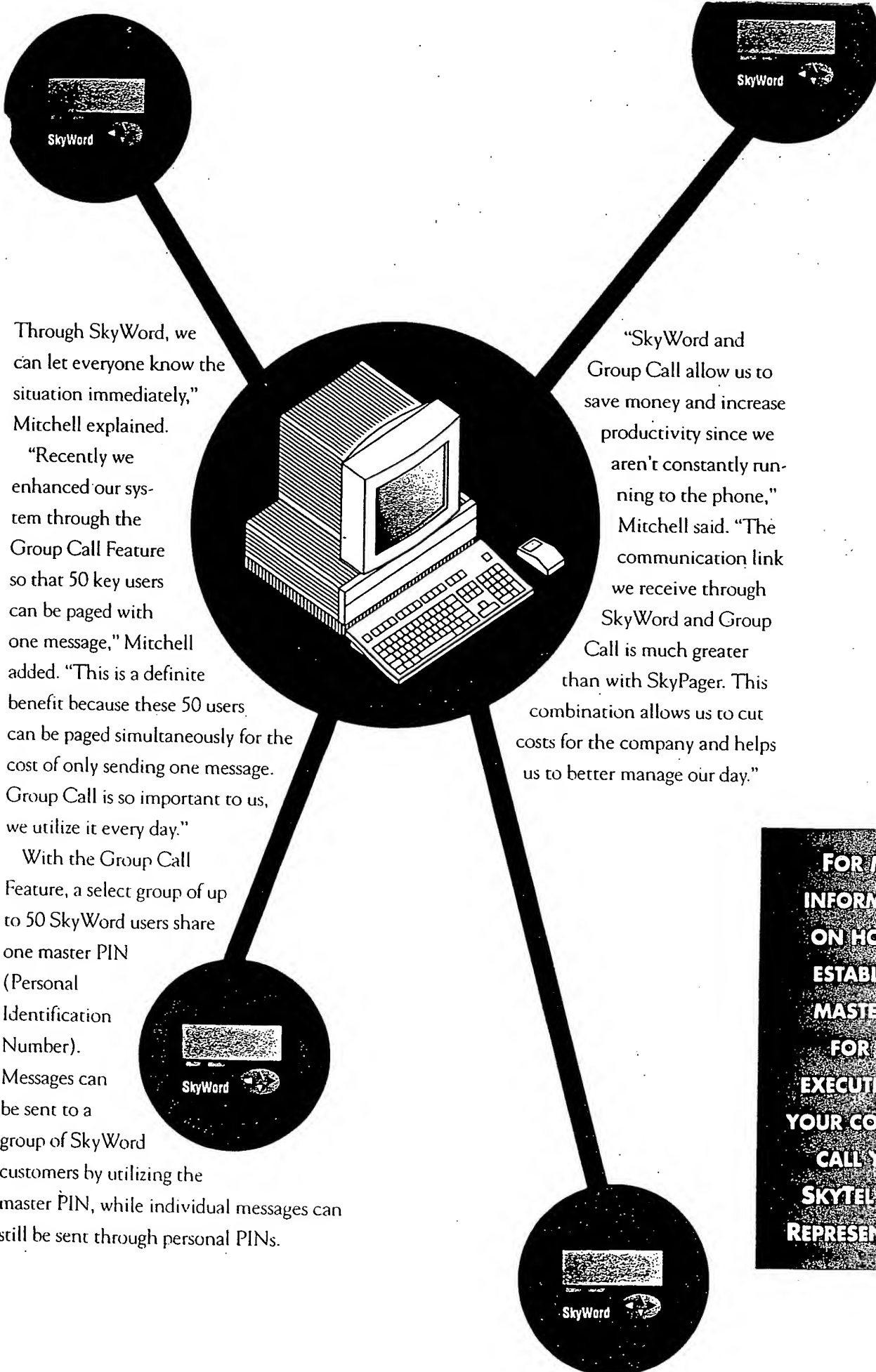
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Through SkyWord, we can let everyone know the situation immediately," Mitchell explained.

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With the Group Call Feature, a select group of up to 50 SkyWord users share one master PIN (Personal Identification Number). Messages can be sent to a group of SkyWord customers by utilizing the master PIN, while individual messages can still be sent through personal PINs.

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INFORMATION
ON HOW TO
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EXECUTIVES IN
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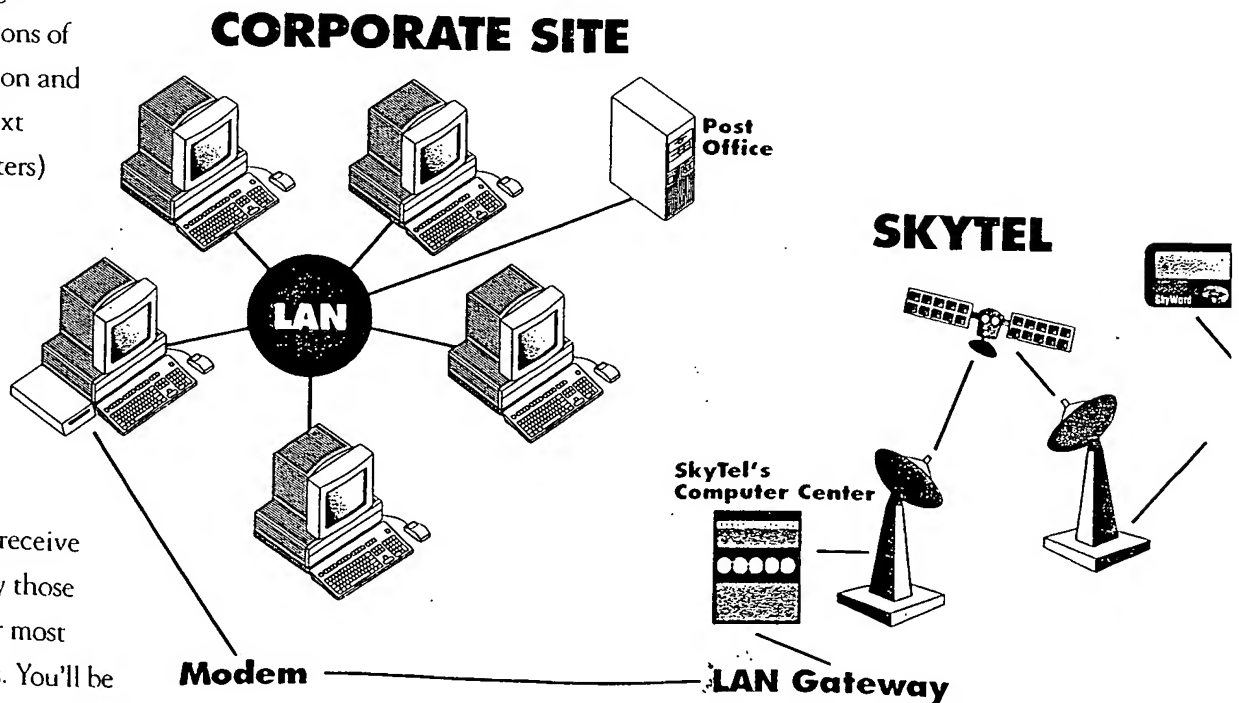
If your E-Mail system allows message filtering, you can choose to receive notification of only those messages from your most important contacts. You'll be

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SkyMail allows you to stay in touch at all times. Whether you're on the road or waiting for an update before your sales presentation, you'll receive the information you need to make informed decisions. And if you travel out of coverage range, you can check your messages through Page Recall (Function 5 from the Paging Menu).

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Providing unsurpassed customer service is a top priority at SkyTel. Whether your question concerns adding new products and services to your messaging plan, expanding your coverage options, or obtaining current account information, SkyTel Customer Service Representatives are available to help 24 hours a day, including weekends and holidays.

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Coverage in Malaysia creates one more link to the Association of Southeast Asian Nations (ASEAN) Region, forecasted to be one of the world's fastest-growing business areas over the next decade.

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SKYTEL SYSTEM

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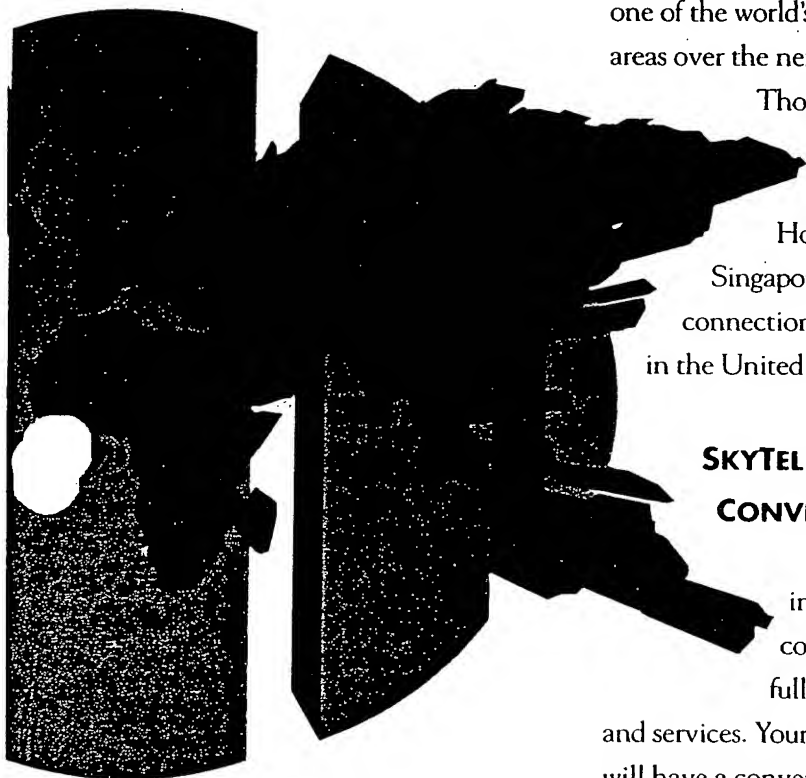
SkyTel also offers three international coverage options: Simulcast Service, Follow-Me Service, and On-Demand Service, allowing you to choose the plan that best suits your messaging needs based on your international travel pattern.

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Mobile
Montgomery

ALASKA

Anchorage
Fairbanks

ARIZONA

Flagstaff
Glendale
Mesa
Phoenix
Scottsdale
Tempe
Tucson

ARKANSAS

Bentonville
Ft. Smith
Little Rock
North Little Rock
West Memphis

CALIFORNIA

Alhambra
Alameda
Anaheim
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Baldwin Park
Bellflower
Berkeley
Box Springs
Buena Park
Burbank
Canyon
Cerritos
Chula Vista
Compton
Concord
Costa Mesa
Daly City
Downey
El Cajon
El Monte
Escundido
Fairfield
Fountain Valley
Fremont
Fresno
Fullerton
Garden Grove
Glendale
Hawthorne
Hayward
Huntington Beach
Inglewood
Irvine
La Mesa
Laguna Niguel
Lakewood
Long Beach
Los Angeles
Malibu
Modesto
Montebello
Monterey
Monterey Park
Mountain View
Naples
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Norwalk
Oakland
Oceanside
Ontario
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Oxnard
Palm Springs
Palo Alto
Pasadena
Pebble Beach
Petaluma
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Rancho Cucamonga
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Redwood City
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San Marcos
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Santa Clara
Santa Cruz
Santa Maria
Santa Monica
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Seaside
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South Lake Tahoe
Stockton
Sunnyvale
Temecula
Thousand Oaks
Torrance
Vacaville
Vallejo
Ventura
Walnut Creek
West Covina
Westminster
Whittier

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Aurora
Boulder
Colorado Springs
Denver
Englewood
Ft. Collins
Lakewood
Vail
Westminster

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Danbury
Darien
Fairfield
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Meriden
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New Britain
New Haven
New London
Norwalk
Stamford
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Waterbury
West Haven

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Wilmington

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Ft. Pierce
Ft. Walton Beach
Gainesville
Hialeah
Hollywood
Homestead
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Key West
Kissimmee
Lake City
Lakeland
Largo
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Melbourne
Miami
Miami Beach
Naples
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Tallahassee
Tampa
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Overland Park
Wichita

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Covington
Lexington
Louisville

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Bossier City
Houma
Kenner
Lafayette
Lake Charles

La Place

Metairie
New Orleans
Shreveport
Slidell

MAINE

Kennebunkport
Portland

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Emmitsburg
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Haverhill
Lawrence
Lowell
Lynn
Malden
Maynard
Medford
New Bedford
Newton
Pittsfield
Plymouth
Quincy
Salem
Somerville
Springfield
Waltham
Woburn
Worcester

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Dearborn
Dearborn Heights
Detroit
East Lansing
Flint
Grand Rapids
Jackson
Kalamazoo
Lansing
Livonia
Pontiac
Roseville
Royal Oak
Saginaw
Southfield
St. Clair Shores
Sterling Heights
Taylor
Warren
Westland
Wyoming

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Burnsville
Eden Prairie
Minneapolis
Rochester
St. Paul

MISSISSIPPI

Biloxi
Jackson
Oxford

MISSOURI

Columbia
Florissant
Independence
Kansas City
Springfield
St. Louis

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Lincoln
Omaha

NEVADA

Las Vegas
Reno

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Manchester
Nashua

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Bayonne
Bergen
Bernardsville
Camden
Cherry Hill
Clifton
East Orange
Elizabeth
Hackensack
Hackettstown
Hamilton
Irvington
Jersey City
Mahwah
Middlesex
Middletown
Moonmouth
Morristown
Newark
Old Bridge
Passaic
Paterson
Princeton
Somerset
Somerville
Toms River
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Las Cruces
Los Alamos
Santa Fe

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Amherst
Babylon
Binghamton
Brookhaven
Buffalo
Cheektowaga
Clay
Grand Island
Hamburg
Hampton
Islip
Middletown
Mount Vernon
Nassau
New Rochelle
New York City
Niagara Falls
North Hempstead
Oyster Bay
Peekskill
Portchester
Poughkeepsie
Rochester
Rockland
Rome
Schenectady
Smithtown
Suffolk
Syracuse
Tonawanda
Troy
Union
Utica
West Seneca
Westchester
White Plains
Yonkers

NORTH CAROLINA

Asheville
Burlington
Charlotte
Durham
Fayetteville
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High Point
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Wilmington
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Canton
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Columbus
Dayton
Elmhurst
Euclid
Findlay
Hamilton
Kettering
Lakewood
Lorain
Mansfield
Middletown
Parma
Sandusky
Steubenville
Toledo
Youngstown

OKLAHOMA

Norman
Oklahoma City
Tulsa

OREGON

Corvallis
Eugene
Portland
Salem

PENNSYLVANIA

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Bethlehem
Carlisle
Erie
Gettysburg
Harrisburg
Hershey
King of Prussia
Lancaster
Philadelphia
Pittsburgh
Reading
Scranton
State College
West Chester
Wilkes Barre
York

PUERTO RICO

Caguas Valley
San Juan

RHODE ISLAND

Cranston
East Providence
Pawtucket
Providence
Warwick

SOUTH CAROLINA

Charleston
Columbia
Florence
Greenville
Hilton Head
Myrtle Beach
North Charleston
Spartanburg

SOUTH DAKOTA

Sioux Falls

TENNESSEE

Bartlett
Brentwood
Chattanooga
Johnson City
Kingsport
Knoxville
Memphis
Morristown
Nashville

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Arlington
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Brownsville
Bryan
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Denton
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Garland
Grand Prairie
Harlingen
Houston
Irving

Killeen

Laredo
Lewisville
Lubbock
McAllen
Mesquite
Midland
Mission
Odessa
Pasadena
Plano
Possum Kingdom
Richardson
San Angelo
San Antonio
Sheiman
Tyler
Waco
Wichita Falls

UTAH

Ogden
Orem
Provo
Salt Lake City
Sandy City
West Valley

VERMONT

Burlington

VIRGIN ISLANDS

St. Thomas

VIRGINIA

Alexandria
Arlington
Bailey's Crossroads
Berryville
Charlottesville
Chesapeake
Fairfax
Fredericksburg
Hampton
Manassas
Marina Towers
Newport News
Norfolk
Portsmouth
Quantico
Richmond
Roanoke
Vienna
Williamsburg
Winchester
Woodbridge

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Bellevue
Bellingham
Everett
Lakewood
Olympia
Seattle
Spokane
Tacoma
Vancouver
Yakima

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Charleston
Huntington
Wheeling

WISCONSIN

Appleton
Green Bay
Kenosha
Madison
Milwaukee
Oshkosh
Racine
Somers
Wausau
West Allis

WYOMING

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To receive extra copies of The SkyTel Update, call 1-800-SKY-USER. Please also let us know of any address changes.

APPENDIX B

UNITED NETWORK FOR ORGAN SHARING (UNOS)

GST FRAMEWORK

INTERRELATIONSHIP

- UNOS ↔ HHS, Div. of Transplantation
 - UNOS ↔ Health Care Financing Administration
 - UNOS ↔ Congress
 - UNOS ↔ Transplant Centers
 - UNOS ↔ Transplant Suregons
 - UNOS ↔ Transplant Coordinators
 - UNOS ↔ Organ Donors and Families
 - UNOS ↔ Organ Procurement Organizations (OPO)
 - UNOS ↔ Donor Organ Recovery Teams
 - UNOS ↔ Donor Hospitals
 - UNOS ↔ Professional Societies and Associations
 - UNOS ↔ Transplant Recipient Advocacy Groups
 - UNOS ↔ Scientists and Researchers
 - UNOS ↔ Medical Professionals
 - UNOS ↔ Major Pharmaceutical Manufacturers
 - UNOS ↔ Major Pharmacies
 - UNOS ↔ Transplant Recipients
 - UNOS ↔ Public
 - UNOS ↔ Media
-
- Organ Donors and Families ↔ OPO
 - Organ Donors and Families ↔ Donor Hospital
 - Organ Donors and Families ↔ Donor Organ Recovery Teams
 - Organ Donors and Families ↔ Transplant Recipient Advocacy Groups
 - Organ Donors and Families ↔ Transplant Recipients
 - Organ Donors and Families ↔ Media
-
- OPO ↔ Donor Hospitals
 - OPO ↔ Donor Organ Recovery Teams
 - OPO ↔ Transplant Centers
 - OPO ↔ Transplant Suregons
 - OPO ↔ Transplant Coordinators

OPO ↔ Professional Societies and Associations
OPO ↔ Transplant Recipient Advocacy Groups
OPO ↔ Transplant Recipients
OPO ↔ Public
OPO ↔ Media

Transplant Recipients ↔ Transplant Centers
Transplant Recipients ↔ Transplant Suregons
Transplant Recipients ↔ Transplant Coordinators
Transplant Recipients ↔ Transplant Recipient Advocacy Groups
Transplant Recipients ↔ Medical Professionals
Transplant Recipients ↔ Major Pharmacies
Transplant Recipients ↔ Public
Transplant Recipients ↔ Media
Transplant Recipients ↔ Donor Hospitals

Transplant Centers ↔ HHS, Div of Transplantation
Transplant Centers ↔ Congress
Transplant Centers ↔ Transplant Suregons
Transplant Centers ↔ Transplant Coordinators
Transplant Centers ↔ Professional Societies and Associations
Transplant Centers ↔ Transplant Recipient Advocacy Groups
Transplant Centers ↔ Scientists and Researchers
Transplant Centers ↔ Medical Professionals
Transplant Centers ↔ Major Pharmaceutical Manufacturers
Transplant Centers ↔ Major Pharmacies
Transplant Centers ↔ Public
Transplant Centers ↔ Media

HOLISM

Government
Transplant Centers
Transplant Suregons
Transplant Coordinators
Organ Donor and Families
OPO
Transplant Recipient Advocacy Groups
Transplant Recipients

GOAL-SEEKING

Return chronically ill patients to productive and fulfilling lives
Profit
Research
Enhance image of Hospitals
Decrease deaths

INPUTS

Patients
Money
Doctors
Suppliers
Organ Donors
Laws
Regulations
Taxes
Interns
Residents
Trauma Victims

OUTPUTS

Patients with improved health
Employment
Deceased patients
Discarded organs
Research
Improved procedures
Laws
Regulations
Educated doctors

TRANSFORMATION

Contracts and Grants
Education
Member Services
Policy Development
Research
Business
Development
Communications
Computer Services
Planning
Committee Liaisons

Transplant Center Operations
Procurement of Organs
Patient Requests and Priorities
Organ Removal and Security
Donor and Recipient Medical History and Assessment
On-line and Download Donor Data

ENTROPY

Untimely Organ Matching
Deaths
Lawsuits
Dissatisfied persons (candidates, recipients, members, govt. representatives, etc.)
Unused Organs

REGULATION

National Organ Transplant Act (NOTA)
National Anatomical Gift Act
State donor laws
Restriction from local Medical Examiners
Federal regulation
Federal Contracts
Unos Board of Directors' adopted policies

HIERARCHY (Organizational Chart enclosed)

Public
Congress
HHS, Div. of Transplantation
Unos Members
Unos Board of Directors
Unos President
Executive Director
Asst. Executive Director
Functional Areas

DIFFERENTIATION

Contracts and Grants
Education
Member Services
Policy Development
Research
Business
Development
Communications
Computer Services
Planing
Committee Liasions

EQUIFINALITY

Transplant candidates receive transplant and live or die
Transplant candidates do not receive transplants and die
Transplant Recipients become productive or remain dependent on others

INTRAOPERATIVE MANAGEMENT

UNOS United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

Enter OR Date/Time:
Incision Date/Time:

Exit OR Date/Time:
Clamp Date/Time:

	Average	Low	Duration	High	Duration
BP					
HR					

Average Urine Output: cc/hr
Last Hour Urine Output: cc
Total Urine Output: cc

MEDICATIONS

Drug Name	Dosage	Time

☐ Vasodilators
☐ Vasopressors

Drug	Dosage	Time

BLOOD PRODUCTS

Type	Volume

CRYSTALLOIDS

Type	Volume

Comments:

OR TEAMS

Heart	Heart/Lung	Right Lung	Left Lung
Liver	Kidneys	Pancreas	Intestine
Anesthesia	Circulator	Scrubs	Other:

Document Information

Date/Time composed: 01/23/95 02:52:53 PM

Original Document Author: Audrey Neilsen/UNOS

Author Access: OIS Organ Center; Audrey Neilsen/UNOS

Reader Access: Audrey Neilsen/UNOS; UNOS

MATCH RUN INPUT**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID: IAW054	Donor Name: Mary Doe
-----------------------------------	-----------------	----------------------

LOCAL INPUT VARIANCES

na:	
na:	

OPO Center Code: GAMC
Donor Hospital Zip Code: 23456

Donor Center Name: Medical College Of Georgia Hospital
Donor Provider Number:

User Initials: AN

Donor Age: 25

Donor Age Unit: Years

Donor Weight: 120

Donor Weight Unit: Pounds

Donor Height: 60

Donor Height Unit: Inches

Donor Race: White

Donor Sex: Female

A1: 10 A2: 10 B1: 14 B2: 14 DR1: 5 DR2: 5

ABO: A1

Match Run Organs: HR, KI, LI, LU, PA, IN, HL, KP

Kidney Side Code: Both

Is There Time to Run a Cross Match? No

Should Tray Data Be Used? No

Previous Gastrointestinal Disease: No

Hepatitis Positive: Negative

How many lines (including headers) of the Match Run Output
would you like to have initially available?

Organ	Default Number of Output Lines
HR or HL	50
KI	100
LI	50

Organ	Default Number of Output Lines
LU	50
PA or KP	50
IN	30

Document Information

Date/Time composed: 01/23/95 01:17:30 PM

Document Author: Audrey Neilson/UNOS

Match Run Status: SUCCESS

Reason Why Match Was Re-Run:

Author Access:

Reader Access: Audrey Neilson/UNOS; UNOS; OIS Organ Center; Audrey Neilson/UNOS

DOPS	Time	Other	L	R	DONOR INFORMATION	Retrieval Date and Time
Date	Offering Center	Telephone Number	Contact Person	Donor Center		

- ☐ SEOPF ☐ SIX ANTIGEN ☐ REGION 2 ☐ ACTIVE EXTRA-RENAL ☐ POINT SHARE
☐ Retrieval ☐ Import ☐ Pay Back ☐ Organ Referral ☐ Tissue Only Referral

OPO Case # _____ UNOS ID # _____ Med Rec # _____
 Recovery Date ____/____/____ Coordinator Name _____

DONOR INFORMATION

Donor Hospital _____ Provider No. _____ Hosp. Unit _____
 City/State _____ Telephone # _____
 Date/Time Admission ____/____/____ Attending Physician _____
 Date/Time of Referral ____/____/____ Referring Person _____

Donor Name _____
 SSN _____
 Age _____ Sex _____ Race _____
 Date of Birth ____/____/____ Ht. _____ Wgt _____
 ABO ____ Sub ____ HLA A ____ B ____ DR ____
 Home City _____
 Home State _____ Citizenship _____
 Zip Code _____

Cause of Death _____
 Autopsy ☐ yes ☐ no
 Death Pronounced ☐ yes ☐ no MD _____
 Method _____
 Date ____/____/____ Time _____
 Medical Examiner/Coroner's Case ☐ yes ☐ no
 If yes, ME Restrictions/Denial _____
 Name of ME/Coroner _____
 Time of ME Contact _____

Consent was obtained for all organs? ☐ yes ☐ no If no, reason _____
 Donor card driver's license? ☐ yes ☐ no ☐ unknown
 Next of kin (NOK) name: _____ Relationship: _____
 NOK address: _____ NOK Telephone No. _____

Consent given for organs: HR LU HL LI K PA Other
 Consent given for tissue: F SK B/T HV SV Other
 Consent for research: ☐ yes ☐ no Consent obtained by _____

Admission Course/Comments

Patient Name _____

UNOS ID # _____

INITIAL PHYSICAL ASSESSMENT

PULMONARY

Date _____ Time _____

TUBES: ☐ Endotracheal ☐ Tracheostomy ☐ Left Chest ☐ Right Chest

BREATH SOUNDS: ☐ even ☐ uneven ☐ absent left/right
☐ clear ☐ rales left/right ☐ rhonchi left/right

CARDIOVASCULAR

LINES: ☐ PA cath ☐ CVP ☐ Arterial line
 HEART RHYTHM: ☐ regular ☐ irregular
 HEART TONES: ☐ normal ☐ murmur ☐ rub
 PERIPH. PULSES: ☐ present 1 2 3 4 ☐ absent
 PERIPH. EDEMA: ☐ present 1 2 3 4 ☐ absent

SKIN

☐ pink ☐ dusky
☐ warm ☐ cool
☐ bruises ☐ lacerations ☐ abrasions
☐ tattoos ☐ track marks

Temperature _____ °

GASTROINTESTINAL

DPL: ☐ yes ☐ no

Result _____

TUBES: ☐ ng ☐ gastrostomy ☐ surgical drains

ABDOMEN: ☐ incisions ☐ surgical scars ☐ other scars (describe below)
☐ soft ☐ firm ☐ non-distended ☐ distended
☐ + bowel ads ☐ no bowel ads

GENITO URINARY

URINE VOLUME: ☐ <100 cc/hr ☐ 100-500 cc/hr ☐ > 500 cc/hr ☐ anuric

APPEARANCE: ☐ clear ☐ cloudy ☐ hematuria

MUSCULOSKELETAL

FRACTURES: ☐ closed ☐ compound/open ☐ dressings/splints ☐ Traction ☐ none

Please identify any injuries, fractures, incisions, tattoos, social indicators on the diagrams and describe below.

Please discuss hospital history (include injuries, arrests, OR procedures, infections, etc.)

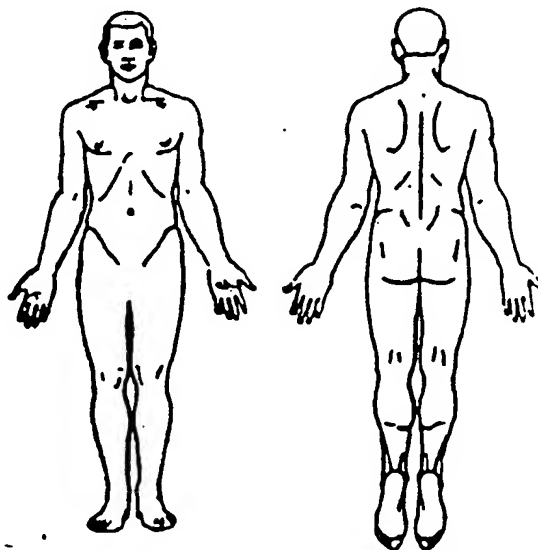
☐ Cardiac/Respiratory Arrest (downtime) _____

☐ Chest compressions (time) _____

☐ OR Procedures _____

☐ Defibrillation _____

Comments: _____



Patient Name _____

UNOS ID # _____

MEDICAL/SOCIAL HISTORY

Please complete. Any YES requires detailed explanation in comments section including frequency, duration, recent history, and additional comments.

Has the patient had a history of:	YES	NO	UNK	COMMENTS
1. Liver Disease				
Hepatitis				
Cirrhosis				
2. Kidney Disease				
3. Hypertension				Duration:
4. Heart Disease				
5. Diabetes				Insulin <input type="checkbox"/> YES <input type="checkbox"/> NO
6. Cancer				
7. Neurological Disease				
Meningitis				
Dementia				
8. Pulmonary Disease				
TB				
9. Previous Surgery				
Type and Date				
10. Drug or Substance Abuse				
IV				
ETOH				
Tobacco				# packs per day
11. Received Previous Blood Transfusion				Year
12. Received Human Pituitary Growth Hormone (Pit-hgh)				
13. Homosexual/Bisexual/High HIV Risk Sexual Partner				
14. Unexplained Weight Loss/Recent Flu-Like Symptoms				
Persistent Diarrhea				
15. Immunized/Vaccinated Last 6 Months				
16. Auto-immune Disease				
17. Persistent Cough or Fever				
18. Allergies				
19. Arthritis or Joint Disease				
20. Prolonged Steroid Use				
21. Other pertinent medical information (under comments)				

Personal Physician's name: _____ Donor's Occupation _____

Respondent name: _____ Relationship _____

Medications: _____

Comments: _____

Patient Name _____

UNOS ID # _____

LAB PROFILE

LAB DATA		Admit				Final	URINALYSIS		Initial		Final	CBC & Diff		Admit		Final	
Date							Date					Date					
Time							Time					Time					
Na+ 134-145							Color					RBC					
K+ 3.5-5.0							Appearance					WBC 5-10					
Cl- 95-105							pH					Segs					
BUN 10-25							Spec. Grav.					Lymphs					
Creatinine 5-15							Protein					Bands					
Glucose 70-110							Glucose					Monos					
Calcium							Blood										
Phosphorus							RBC					Eos					
Bilirubin 1-1.2 (tot/dir)							WBC										
SGOT/AST 5-40							Epith.										
SGPT/ALT 5-35							Casts					Hgb 12-18					
GGT 10-38							Bacteria					Hct 36-50					
Mg++							Comments					150-400 Platelets					
Alk Phos 20-90																	
LDH 150-450																	
PT 11-15																	
PTT 20-35																	
CPK (tot/MB)	/	/	/	/	/	/											
Amylase 5-40																	
Lipase																	
SEROLOGY							MICROBIOLOGY										
+R=Reactive		NR=Non-Reactive					CULTURES			DATE	RESULTS						
N/A=Not Applicable		PRE	POST				Blood										
Date/Time							Blood										
Anti-HIV I							Urine										
Anti-HIV II							Sputum										
Anti-HTLV I							Sputum Gram Stain										
Anti-HTLV II							CSF										
RPR-VDRL							R. Ureter										
Anti-CMV							L. Ureter										
HBsAg							Kidney Slush										
Anti-HBC							Other										
Anti-HCV							Comments:										
Other																	
Other																	

Patient Name _____

UNOS ID # _____

HEMODYNAMICS/TEMPERATURE

Date	Avg. BP	Low B/P & Dur	Heart Rate	CVP	PAWP	PA	C.O.	Peak Temperature/ duration
		/						/
		/						/
		/						/
		/						/
		/						/
		/						/

Descriptive
note when
not a 24-
hour total*

INTAKE

OUTPUT

Date	Crystalloid Amount	Colloid Amount	Blood Products Type/Amt	24 hr. Total / Hourly Average	24 hr. Urine Output / Hr Avg	Other Amt: Non- Urine Output	24 hr. Total: Urine & Non-Urine Output	Lowest U.O. per hour & duration
			/					
			/					
			/					
			/					
			/					

INOTROPIC SUPPORT

DRUGS	Date/Time Started	Dosage	Peak Dose/Dur	Date/Time Stopped

Patient Name _____

UNOS ID # _____

CARDIAC DATASee page 10 ☐ YES ☐ NO**EKG**

Date/Time ____ / ____ Interpretation _____

Consulting Physician: _____

ECHO

Date/Time ____ / ____ Interpretation _____

E/F _____

CVP ____ BP ____ / ____ HR ____ Heart Rhythm ____ Pressors ☐ YES ☐ NO

Drug _____ Dosage _____ Consulting Physician _____

ANGIOGRAPHY

Date/Time ____ / ____ Interpretation _____

Consulting Physician _____

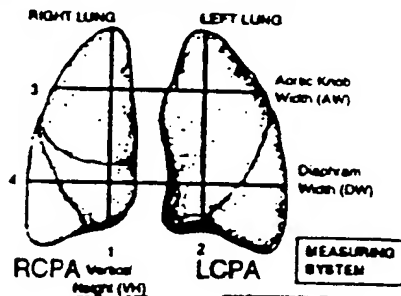
* Use page 10 if more space is required for interpretation

PULMONARY DATA

CXR Date/Time ____ / ____ Interpretation/Comment _____

Change from previous CXR ☐ yes ☐ no _____

CXR Date/Time ____ / ____ Interpretation/Comment _____

Change from previous CXR ☐ yes ☐ no _____**CHEST MEASUREMENTS**

1. Length of Right Lung _____
2. Length of Left Lung _____
3. Aortic Knob Width _____
4. Diaphragm Width _____
5. Chest circumference/Landmark _____
6. Distance from RCPA to LCPA _____

ARTERIAL BLOOD GASES

Date/Time	pH	pCO ₂	pO ₂	HCO ₃	O ₂ Sat	FiO ₂	Rate	TV	PEEP	Hgb
/										
/										
/										
/										
/										
/										
/										
/										
/										

Patient Name _____

UNOS ID # _____

MEDICATIONS

List **ALL** medications other than inotropes given during hospital course and donor management

MEDICATIONS	Date/Time Started	Dosage	Date/Time Stopped	Total Amount

Comments _____

INTRAOPERATIVE MANAGEMENT

Incision Date/Time _____ / _____ Circle Zone (EST) (CST) (MT) (PST)
 Clamp Date/Time _____ / _____ Circle Zone (EST) (CST) (MT) (PST)
 Exit OR Date/Time _____ / _____ Circle Zone (EST) (CST) (MT) (PST)

Average BP: _____ Low BP: _____ Duration: _____ High BP: _____ Duration: _____
 Average HR: _____ Low HR: _____ Duration: _____ High HR: _____ Duration: _____
 Average Urine Output _____ cc/hr Last Hour Urine Output _____ cc/hr Total Urine Output in OR _____ cc

Medications:

<input type="checkbox"/> Heparin	Dosage _____	<input type="checkbox"/> Vasodilators	Drug _____	Dosage _____
<input type="checkbox"/> Thorazine	Dosage _____	<input type="checkbox"/> Vasopressors	Drug _____	Dosage _____
<input type="checkbox"/> Mannitol	Dosage _____		Drug _____	Dosage _____
<input type="checkbox"/> Lasix	Dosage _____		Drug _____	Dosage _____
<input type="checkbox"/> Solumedrol	Dosage _____		Drug _____	Dosage _____
<input type="checkbox"/> Other _____	Dosage _____		Drug _____	Dosage _____
<input type="checkbox"/> Other _____	Dosage _____	<input type="checkbox"/> Blood Products	Type/Volume _____ / _____	



Comments: _____

Patient Name _____

UNOS ID # _____

Clamp Time _____ Circle Zone (EST) (CST) (MT) (PST) Warm Ischemic Time ☐ yes ☐ no Duration _____In situ Flush ☐ yes ☐ no Flush Solution _____ Volume _____ Flush Characteristics 1+ 2+ 3+ 4+Storage Solution _____ Backtable Flush ☐ yes ☐ no En Bloc ☐ yes ☐ noTyping Materials: ☐ Nodes ☐ Spleen ☐ Blood Clot ☐ Cell Prep ☐ T Cell ☐ B Cell

LEFT KIDNEY ANATOMY					RIGHT KIDNEY ANATOMY				
<input type="checkbox"/> Txp <input type="checkbox"/> Rsrch <input type="checkbox"/> Disc <input type="checkbox"/> Not Recovered					<input type="checkbox"/> Txp <input type="checkbox"/> Rsrch <input type="checkbox"/> Disc <input type="checkbox"/> Not Recovered				
Comments			cm	length	cm	Comments			
			cm	width	cm				
				weight					
				# arteries #					
	cm	cm	cm	length	cm	cm	cm		
	mm	mm	mm	diameter	mm	mm	mm		
				distance apart					
				aortic cuff					
				# veins #					
	cm	cm	cm	length	cm	cm	cm		
	mm	mm	mm	diameter	mm	mm	mm		
				distance apart					
				caval cuff					
				# ureters #					
	cm	cm		ureter length	cm	cm			

LEFT KIDNEY	LEFT	RENAL ANATOMY	RIGHT	RIGHT KIDNEY
	<input type="checkbox"/> yes <input type="checkbox"/> no	Aortic plaque	<input type="checkbox"/> yes <input type="checkbox"/> no	
	<input type="checkbox"/> yes <input type="checkbox"/> no	Arterial plaque	<input type="checkbox"/> yes <input type="checkbox"/> no	
	<input type="checkbox"/> yes <input type="checkbox"/> no	Infarcted area	<input type="checkbox"/> yes <input type="checkbox"/> no	
	<input type="checkbox"/> yes <input type="checkbox"/> no	Capsule intact	<input type="checkbox"/> yes <input type="checkbox"/> no	
	<input type="checkbox"/> yes <input type="checkbox"/> no	Subcapsular hematoma	<input type="checkbox"/> yes <input type="checkbox"/> no	
	<input type="checkbox"/> yes <input type="checkbox"/> no	Cysts/discoloration	<input type="checkbox"/> yes <input type="checkbox"/> no	
Biopsy <input type="checkbox"/> yes <input type="checkbox"/> no				Biopsy <input type="checkbox"/> yes <input type="checkbox"/> no
Comments		Comments		

Patient Name _____

UNOS ID # _____

HEART DATA ☐ Transplanted ☐ Valves ☐ Research ☐ Discarded ☐ Not Recovered

Cardioplegia _____ Solution _____ Volume _____

Anatomical Abnormality ☐ yes ☐ no Comments _____Surgical Damage ☐ yes ☐ no Comments _____

Recovering Surgeon _____

LUNG DATA ☐ Transplanted ☐ Research ☐ Discarded ☐ Not RecoveredLung Recovered ☐ Right ☐ Left ☐ Heart/Lung ☐ Double Lung

Flush Start _____ Solution _____ Volume _____

Surgical Damage ☐ yes ☐ no Comments: _____Anatomical Abnormality ☐ yes ☐ no Comments: _____

Recovering Surgeon _____

PANCREAS DATA ☐ Transplanted ☐ Islet Cells ☐ Research ☐ Discarded ☐ Not Recovered

Flush Start _____ Solution _____ Volume _____

Whole ☐ yes ☐ no Celiac ☐ yes ☐ no Spleen attached ☐ yes ☐ no Portal ☐ yes ☐ no Other _____Anatomical Abnormality ☐ yes ☐ no Comments _____Surgical Damage ☐ yes ☐ no Comments _____

Recovering Surgeon _____

LIVER DATA ☐ Transplanted ☐ Research ☐ Discarded ☐ Not Recovered

Aortic Flush Start Time _____ Solution _____ Volume _____ Char 1 2 3 4

Portal Flush Start Time _____ Solution _____ Volume _____ Char 1 2 3 4

Precool Start Time _____ Solution _____ Volume _____

Surgical Damage ☐ yes ☐ no Comments: _____Biopsy ☐ yes ☐ no Comments: _____Vessels Sent ☐ yes ☐ no Comments: _____Gall Bladder Incised ☐ yes ☐ noGall Bladder Flushed ☐ yes ☐ no Solution _____ Volume _____

Recovering Surgeon _____

TISSUE DATA	RECOVERED		EXPLANATION IF NO	TECHNICIAN/TISSUE BANK
	YES	NO		
Corneas/Eyes				
Skin				
Bone/Tendon				
Saphenous Vein (indicate #)				
Heart Valve				
Other				

MEDICAL/SOCIAL HISTORY**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

Person interviewed:

Relationship to Deceased:

Do you feel that you know the deceased well enough to answer questions regarding medical/social history?

HYPERTENSION

History of Hypertension:

Duration:

Method of Control

Diet:

Diuretics:

Other Hypertensive Medication:

DIABETES

History of Diabetes:

Duration:

Insulin Dependent:

How long?

CHEMICAL USE

History of Cigarette Use:

(> 20 Pack Years)

Continued Cigarette Use:

(Last 6 Months)

History of Alcohol Dependency:

Continued Alcohol Use:

(Last 6 Months)

IV Drug Use:

Continued IV Drug Use:

(Last 6 Months)

Other Drug Use:

Continued Other Drug Use:

(Last 6 Months)

CANCER

History of Cancer:

Cancer Free Interval: Years

Location of Cancer:

If Other, Specify:

Cancer at Time of Procurement

Intracranial:

Extracranial:

Skin:

QUESTIONS	ANSWER	COMMENTS
1. Did the deceased have any history of heart disease, high blood pressure, or chest pain? Poor circulation especially in the legs? Take any drugs for heart or B/P problems? If so, what?		
2. Did the deceased suffer from any type of liver disease? Any history of yellow jaundice? Been told they had type of Hepatitis? Any contact with persons diagnosed with Hepatitis?		
3. Did the deceased suffer from any type of neurological or brain disease such as Alzheimer's, seizures, periods of confusion or recent memory loss, history of brain tumor?		
4. Did the deceased have any kidney related disease? Kidney stones? Frequent infections? Ever been treated with kidney dialysis?		

5. Did the deceased have a history of diabetes? How many years? Required oral medication or insulin injections? How many years?		
6. Did the deceased have a history of digestive or intestinal problems? Ever have bloody stools or intestinal surgery?		
7. Did the deceased have any history of arthritis or joint disease? History of broken bones? Any complaints of stiff or sore joints?		
8. Did the deceased have any history of asthma, emphysema, or any lung disease? Ever have a positive skin test for Tuberculosis? Ever treated for TB?		
9. Has the deceased been seen by a physician or hospitalized in the past two years? What physician and/or what hospital?		
10. Has the deceased ever had cancer or received radiation therapy or drugs for cancer?		
11. Has the deceased ever had any past surgical procedures? Please name them.		
12. Has the deceased experienced any periods of explained or unexplained weight loss?		
13. Did the deceased ever use illegal drugs or other substances? (i.e., cocaine, marijuana)		
14. Has the deceased ever received blood transfusions or blood products prior to this admission?		
15. Has the deceased ever been refused as a blood donor or told not to donate? Why?		
16. Did the deceased ever receive an organ or tissue transplant? (i.e., bone, cornea, skin, heart, kidney)		
17. In the past 12 months did the deceased have a tattoo, ear piercing, acupuncture, or accidental needle stick?		
18. Was the deceased vaccinated for Hepatitis B?		
19. In the past 4 weeks was the deceased vaccinated for any reason?		
20. Was the deceased ever given growth hormone?		
21. What medications, if any did the deceased take on a regular basis?		
22. Did the deceased use tobacco products? Cigarettes? Packs/day? For how long? Other tobacco products?		
23. Did the deceased drink alcohol? How much? What type? For how long?		
24. Has the deceased ever been exposed to toxic substance? (i.e., lead, pesticides)		
25. In the past 12 months, was the deceased diagnosed with or treated for syphilis or gonorrhea, or have a reactive screening test for syphilis in the absence of a negative confirmatory test?		
26. Has the deceased ever been in jail? If so, how long and where?		

27. Has the deceased ever been in a long term care facility? If so, how long and where?		
28. Has the deceased ever engaged in sex for money or drugs? Did the deceased ever have sex with anyone who had?		
29. Male Donors: Has the deceased ever had sex with another male even one time?		
30. Female Donors: Has the deceased ever had sex with a male who has had sex with another male?		
31. Has the deceased ever used a needle to inject drugs into their veins, muscle, or under their skin for nonmedical use? Did the deceased ever have sex with anyone who had?		
32. Did the deceased ever have sex with a person known or suspected to have HIV infection?		
33. Has the deceased ever received clotting factor concentrates for hemophilia or other bleeding disorders? Did the deceased ever have sex with anyone who had?		
34. Was the deceased ever exposed to known or potentially HIV-infected blood through accidental needle-stick or through contact with an open wound, non-intact skin, or mucous membrane in the past 12 months?		

ADDITIONAL COMMENTS (please refer to the question numbers where applicable):

Document Information

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CONSENT & ADMISSION**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11.03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

Date of Consent: 01/15/95
Time of Consent: 08:00 PM

Approached by: Social Worker
If other, please specify:

NEXT OF KIN INFORMATION

Name: Joe Doe
Relationship to deceased: Brother
Address: 1 Main St.
Phone #: (804)555-1212
Funeral Home: Biley's
Discussion: Yes Permission: Yes

Donor Card: Yes

Tissue Transplant: Yes

Research Consent: No

Tissue Bank Name: Don't know this one

Tissue Bank Coordinator: Mary Smith

Organ	Consent Requested?	Write Reason If consent Not requested	Consent Obtained?	Enter Reason Code If No	Specify If Other
Kidney	Yes		Yes		
Liver	Yes		Yes		
Intestine	Yes		Yes		
Pancreas	Yes		Yes		
Heart	Yes		Yes		
Lung	Yes		Yes		
Tissue	Yes		Yes		

Admission Course/Comments:☒ Cardiac/Respiratory Arrest

Downtime:

☐ Chest Compressions

Duration:

☐ OR Procedures

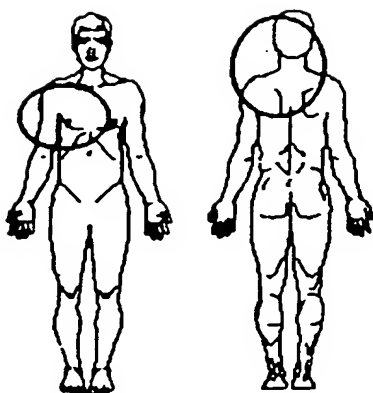
Comments:

☐ Defibrillation

Comments:

Body Diagram

Lookup Key: Man



Hidden Fields
Diagram

Additional Assessment Comments:

Document Information

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CASE INFORMATION**UNOS** United Network
for Organ Sharing

CRS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

<input checked="" type="radio"/> Local
<input type="radio"/> Non Local

<input type="radio"/> Referral Only
<input type="radio"/> Consented But Not Recovered
<input checked="" type="radio"/> Recovered

<input checked="" type="radio"/> Organ Referral Only
<input type="radio"/> Tissue Referral Only
<input type="radio"/> Organ & Tissue Referral

Referral Call Date: 01/13/95

Referral Call Time: 01:02 PM

Recovery Date: 01/15/95

Medical Record #: 12345

OPO and COORDINATOR INFORMATION

First Coordinator's Name: Audrey Nelson

First Coordinator's Phone #: 804-330-8636

Secondary Coordinator's Name:

Second Coordinator's Phone #:

OPO Provider #: 11p001

OPO Name: MEDICAL COLLEGE OF GEORGIA HOS

OPO Center Code: GAMC

HOSPITAL INFORMATION

Admission Date: 01/10/95

Attending Physician: Dr. Spock

Admission Time: 02:30 AM

Referring Person:

Provider #: 11p001

Name: MEDICAL COLLEGE OF GEORGIA HOS

City: AUGUSTA

State: Georgia

Zip Code: 30912

Unit: ICU

Phone #: (804)555-1212

Fax #:

MEDICAL EXAMINER CASE

M.E. Contact Date: 01/14/95

M.E. Contact Time: 10:00 PM

M.E./Coroner Case: No

M.E. Permission for donation: Yes

M.E./Coroner's Name: John Doe

M.E. Case #: 23456

M.E. Restrictions/Denial Reason(s):

BRAIN DEATH

Cause of Death: Head Trauma

Mechanism of Death: Blunt Injury

Other Cause of Death:

Circumstances of Death:

Brain Death Pronounced: Yes

Autopsy: No

Brain Death Method(s) Used:

	MD	Brain Death Date	Brain Death Time
First	something here	01/14/95	07:00 PM
Second			

INFECTION

Clinical Infection: No

If Yes, Complete the following:

Source	Confirmed by Culture?
--------	-----------------------

<input type="checkbox"/> Blood	
<input type="checkbox"/> Pulmonary	
<input type="checkbox"/> Urine	
<input type="checkbox"/> Other	

Document Information

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INITIAL PHYSICAL ASSESSMENT

UNOS United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

Assessment Completion Date: 01/23/95
Assessment Completion Time: 02:05 PM EST

PULMONARY

Tubes:

Endotracheal:

Size:

Tracheostomy:

Left Chest Tube:

#:

Right Chest Tube:

#:

Breath Sounds:

CARDIOVASCULAR

Lines:

Heart Rhythm:

Heart Tones:

Periph. Pulses:

Periph. Edema:

INTEGUMENTARY

Color:

Temp:

Temp Reading:

Observations:

GASTROINTESTINAL

DPL:

Result:

Tubes:

Abdomen:

If Other Scars, Explain:

GENITOURINARY

Urine Volume:

Appearance:

MUSCULOSKELETAL

Fractures:

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UNOS United Network
for Organ Sharing

[illegible]

Antiarrhythmics	
Anticonvulsants	
Antihypertensives	
Antibiotics	
Vasodilators	
Vasopressors	
Dopamine	
Dobutamine	
	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown

Donor Pretreatment

Did donor receive pretreatment medication?

If Yes, Complete the following:

Steroids	
Diuretics	
Thyroxine	
Heparin	

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SEROLOGY**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11 03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

	Pre Transfusion	Post Transfusion
Anti-HIV I		
Anti-HIV II		
Anti-HTLV I		
Anti-HTLV II		
RPR-VDRL		
Anti-CMV		
HBsAg		
Anti-HBC		
Anti-HCV		

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TISSUE DATA**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11.03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

Tissue	Recovered	Explanation, If No	Technician	Tissue Bank
Corneas/Eyes				
Skin				
Bone/Tendon				
Saphenous Ven #				
Heart Valve				
Other				

Document Information

Date/Time composed: 01/23/95 03:03:24 PM

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URINALYSIS

UNOS United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11.03:31	UNOS ID:	Donor Name: Mary Doe
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Urinalysis	1. Initial	2.	3.	4.	5.	6.	7.
Date							
Time							
Color							
Appearance							
pH							
Sp. Grav.							
Protein							
Glucose							
Blood							
RBC							
WBC							
Epith.							
Casts							
Bacteria							

Document Information

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PULMONARY DATA

UNOS United Network
for Organ Sharing

OS ID: 00020-1995/01/23-11:03:31

UNOS ID:

Donor Name: Mary Doe

FIRST CXR

Date: Time:

Interpretation/Comments:

Change from previous CXR:

SECOND CXR

Date: Time:

Interpretation/Comments:

Change from previous CXR:

THIRD CXR

Date: Time:

Interpretation/Comments:

Change from previous CXR:

FOURTH CXR

Date: Time:

Interpretation/Comments:

Change from previous CXR:

FIFTH CXR

Date: Time:

Interpretation/Comments:

Change from previous CXR:

BRONCHOSCOPY

Date: Time:

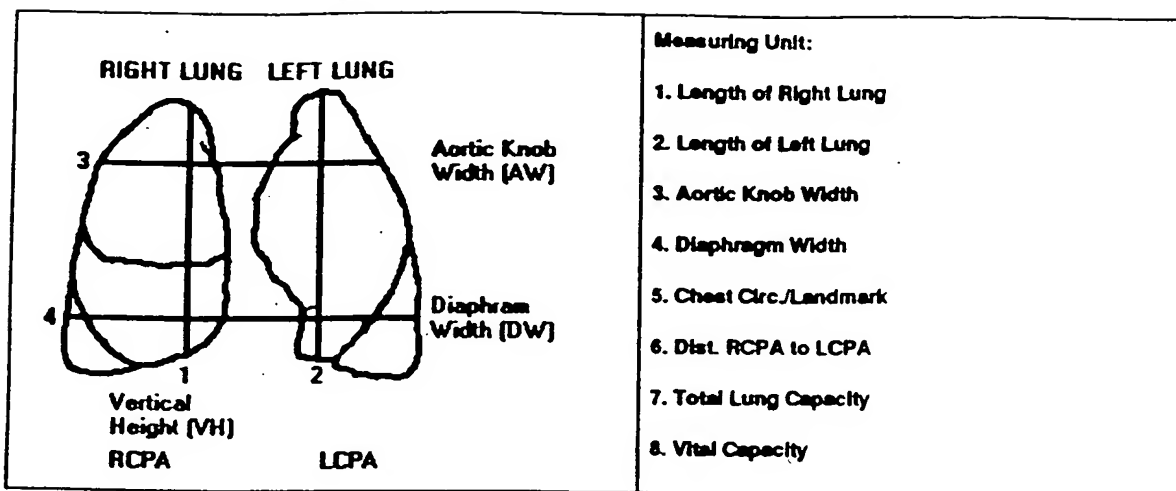
Consulting Physician:

Interpretation:

PULMONARY COMMENTS

Comments:

CHEST MEASUREMENTS



Males	Females
<p>TLC = (0.094 x Ht. CM)-(0.015 x Age in Yrs.)-9.167</p> <p>VC = (0.064 x Ht. CM)-(0.031 x Age in Yrs.)-5.335</p>	<p>TLC = (0.079 x Ht. CM)-(0.008 x Age in Yrs.)-7.49</p> <p>VC = (0.052 x Ht. CM)-(0.018 x Age in Yrs.)-4.36</p> <p>[1 inch = 2.54 cms]</p>

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MICROBIOLOGY**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1895/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
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Culture	Date	24hr Result	Date	48hr Result	Date	Final Result
Blood						
Blood						
Urine						
Sputum GM ST						
Sputum						
CSF						
R. Ureter						
L. Ureter						
Kidney Basin						

Additional Comments:

Document Information

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PANCREAS DATA**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
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Pancreas Recovery:**Not Recovered Reason:****Aortic Flush Start Time:****Solution:****Volume:****Flush Characteristic:****Splenic (in pan) Flush Start Time:****Solution:****Volume:****Flush Characteristic:****S.M.A. (in pan) Flush Start Time:****Solution:****Volume:****Flush Characteristic:****Whole:****Celiac:****Spleen Attached:****Portal Vein:**

Anatomical Abnormality		Comments:
Surgical Damage		Comments:

Recovering Surgeon:**Transplant Program:****Date Recovered:****Time Recovered:****Document Information****Date/Time composed:** 01/23/95 02:59:24 PM**Original Document Author:** Audrey Neilsen/UNOS**Author Access:** OIS Organ Center; Audrey Neilsen/UNOS**Reader Access:** Audrey Neilsen/UNOS; UNOS

ARTERIAL BLOOD GASES**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
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	1. Admit	2.	3.	4.	5.	6.	7.
Date							
Time							
pH							
pCO ₂							
pO ₂							
HCO ₃							
O ₂ Sat							
FIO ₂							
Rate							
TV							
PEEP							
PIP							

	8.	9.	10.	11.	12.	13.	14.
Date							
Time							
pH							
pCO ₂							
pO ₂							
HCO ₃							
O ₂ Set							
FIO ₂							
Rate							
TV							
PEEP							
PIP							

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CARDIAC DATA**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
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EKG

Date:

Time:

Consulting Physician:

Interpretation:

ECHO

Date:

Time:

Consulting Physician:

Interpretation:

CVP:

E/F:

BP: /

HR:

Heart Rhythm:

Pressors:

Drug Name	Drug Dosage

ANGIOGRAPHY

Date:

Time:

Consulting Physician:

Interpretation:

Document Information

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CBC & Diff**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
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CBC & Diff	1. Admit	2.	3.	4.	5.	6.	7.
Date							
Time							
RBC							
WBC							
H _b							
Hct							
Platelets							
Segs							
Lymphs							
Mands							
Monos							
Eos							

CBC & Diff	8.	9.	10.	11.	12.	13.	14.
Date							
Time							
RBC							
WBC							
Hgb							
Hct							
Platelets							
Segs							
Lymphs							
Mands							
Monos							
Eos							

Document Information

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CHEMISTRY

UNOS United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11.03.31	UNOS ID:	Donor Name: Mary Doe
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Lab Data	1. Admit	2.	3.	4.	5.	6.	7.
Date							
Time							
Na+							
K+							
Cl-							
CO ₂							
BUN							
Creatinine							
Glucose							
Calcium							
Phosphorus							
Bilirubin							
SGOT/AST							
SGPT/ALT							
GGT							
Alb/Tot Pro							
Mg/Cholest							
Alk Phos							
LDH							
PT							
PTT							
Amylase							
Lipase							
Creatine Clearance							

Lab Data	8.	9.	10.	11.	12.	13.	14.
Date							
Time							
Na+							
K+							
Cl-							
CO ₂							
BUN							
Creatinine							
Glucose							
Calcium							
Phosphorus							
Bilirubin							
SGOT/AST							
SGPT/ALT							
GGT							
Alb/Tot Pro							
Mg/Cholest							
Alk Phos							
LDH							
PT							
PTT							
Amylase							
Lipase							
Creatine Clearance							

Document Information

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HEMODYNAMICS/TEMPERATURE

UNOS United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

	1. Admit	2.	3.	4.	5.	6.	7.
Date							
Time Range							
Average B/P							
Heart Rate							
High B/P							
Duration							
Low B/P							
Duration							
CVP							
PA							
PAWP							
CO/CI							
Temp							
Inotropes/ vasopressors							
Dosage							

	8.	9.	10.	11.	12.	13.	14.
Date							
Time Range							
Average B/P							
Heart Rate							
High B/P							
Duration							
Low B/P							
Duration							
CVP							
PA							
PAWP							
CO/CI							
Temp							
Inotropes/ vasopressors							
Dosage							

Document Information

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Reader Access: Audrey Neilsen/UNOS; UNOS

INTAKE/OUTPUT**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

INTAKE	1. Admit	2.	3.	4.	5.	6.	7.
Date							
Time							
Crystalloid Amount							
Colloid Amount							
Total Blood Products							
24 Hr Total Hr Avg							
OUTPUT							
24 Hr Urine Output/ Hr Avg							
Other Amt: Non-Urine Output							
24 Hr Total Urine and Non-Urine Output							
Lowest U.O. per Hr & duration							

BLOOD PRODUCTS

Type	Volume	Comments

Document Information

Data/Time composed: 01/23/95 02:43:47 PM

Original Document Author: Audrey Nelson/UNOS

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INITIAL PHYSICAL ASSESSMENT

UNOS United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31

UNOS ID:

Donor Name: Mary Doe

Assessment Completion Date: 01/23/95

Assessment Completion Time: 02:05 PM EST

PULMONARY

Tubes:

Endotracheal:

Size:

Tracheostomy:

Left Chest Tube:

#:

Right Chest Tube:

#:

Breath Sounds:

CARDIOVASCULAR

Lines:

Heart Rhythm:

Heart Tones:

Periph. Pulses:

Periph. Edema:

INTEGUMENTARY

Color:

Temp:

Temp Reading:

Observations:

GASTROINTESTINAL

DPL:

Result:

Tubes:

Abdomen:

If Other Scars, Explain:

GENITOURINARY

Urine Volume:

Appearance:

MUSCULOSKELETAL

Fractures:

Document Information

Date/Time composed: 01/23/95 02:03:33 PM

Original Document Author: Audrey Neilsen/UNOS

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Reader Access: Audrey Neilsen/UNOS; UNOS

LUNG DATA

UNOS United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11.03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

Lung Recovery:

Not Recovered Reason:

Flush Solution:

Volume:

Storage Solution:

Volume:

Anatomical Abnormality		Comments:
Surgical Damage		Comments:

RIGHT LUNG

Recovering Surgeon:

Transplant Program:

Date Recovered:

Time Recovered:

LEFT LUNG

Recovering Surgeon:

Transplant Program:

Date Recovered:

Time Recovered:

Document Information

Date/Time composed: 01/23/95 02:58:25 PM

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Reader Access: Audrey Neilsen/UNOS; UNOS

LIVER DATA**UNOS** United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

Liver Recovery:**Not Recovered Reason:****Aortic Flush Start Time:****Solution:****Volume:****Flush Characteristic:****Portal Start Time:****Solution:****Volume:****Flush Characteristic:****Precool Time Start Time:****Solution:****Volume:****Flush Characteristic:**

Anatomical Abnormality		Comments:
Surgical Damage		Comments:
Bioopsy		Comments:
Vessels Sent		Comments:
Gall Bladder Incised		Comments:
Gall Bladder Flushed		Comments:
Right Hepatic Branch		Comments:

Recovering Surgeon:**Date Recovered:****Transplant Program:****Time Recovered:****Document Information****Date/Time composed:** 01/23/95 03:02:21 PM**Original Document Author:** Audrey Neilsen/UNOS**Author Access:** OIS Organ Center; Audrey Neilsen/UNOS**Reader Access:** Audrey Neilsen/UNOS; UNOS

KIDNEY DATA

UNOS United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11.03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

Clamp Date: Clamp Time:
 Warm Ischemic Time: No Duration: minutes
 In situ Flush:
 Flush Solution: Volume: Flush Characteristics:
 Storage Solution:
 Backtable Flush: Volume:
 En Bloc: Typing Materials:
 Nephrectomy Surgeon: Assistant Surgeon:

Right	RENAL ANATOMY	Left
	Aortic Plaque	
	Arterial Plaque	
	Infarcted Area	
	Capsule Tear	
	Subcapsular Hematoma	
	Cysts/Discoloration	

Right Kidney Diagram

Left Kidney Diagram

Biopsy: ☐ Yes
☐ No

Biopsy: ☐ Yes
☐ No

RIGHT KIDNEY ANATOMY

Recovery Type:

Length			
Width			
Artery(s) #			
Distance Apart			
Aortic Cuff			
Are multiple arteries on a common cuff?			
Length			
Diameter			
Vein(s) #			
Distance Apart			

Patch of Cava	<input type="radio"/> Yes <input type="radio"/> No		
Length			
Diameter			
Ureter			
Length			
Abnormalities			
Surgical Damage			

Biopsy Results:

Comments:

LEFT KIDNEY ANATOMY

Recovery Type:

Length			
Width			
Artery(s) #			
Distance Apart			
Aortic Cuff			
Are multiple arteries on a common cuff?			
Length			
Diameter			
Vein(s) #			
Distance Apart			
Patch of Cava			
Length			
Diameter			
Ureter			
Length			
Abnormalities			
Surgical Damage			

Biopsy Results:

Comments:

Document Information

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HEART DATA

UNOS United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11:03:31	UNOS ID:	Donor Name: Mary Doe
-----------------------------------	----------	----------------------

Heart Recovery:

Not Recovered Reason:

Flush Solution:

Volume:

Storage Solution:

Volume:

Anatomical Abnormality		Comments:
Surgical Damage		Comments:

Recovering Surgeon:

Transplant Program:

Date Recovered:

Time Recovered:

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File Done Prev >Next

MATCH RUN OUTPUT

UNOS United Network
for Organ Sharing

OIS ID: 00020-1995/01/23-11.03.31	UNOS ID: IAW054	Donor Name: Mary Doe
Date: 23011985-513244	Organ: LU	Match Run Number: 01

Enter Edit Mode to Notify
Notification List

Match Run Results

DATE: 23-JAN-95 TIME: 13.24 EASTERN
UNOS LUNG MATCH RESULTS

RUN NUMBER: 1

DONOR ID UI DONOR NAME AGE SR BG A1 A2 B1 B2 DR DR AVAIL ORGANS ES

IAW054 AM DOE MARY 25Y PC A1 10 10 14 14 5 5 NR E1 L1 LU PA IN NL EP B

BR DI CHEST
(HW) (CH)
MCTU MCTU X LF RT TR VT

401 120L N

STATEWIDE ABO IDENTICAL

STATEWIDE ABO COMPATIBLE

LUNG: ZONE A: ABO IDENTICALS

OR	NAME	CNTR	BG	T	K	A	RIN	MAX	PHONE	ENTRY	MAX
										DATE	TIME
BL	SANTULLO L	MYNS	A	1	M	0	99	212 241 7344	11193	22.35	1500
SEN:051380774	CALLED:										
	INFO:										
	RESPONSE:										
	ACPT:										
	RCODE:										
ER	COOK A	PACH	A	2	M	0	99	800 366 4777	61493	06.49	3000
SEN:461376487	CALLED:										
	INFO:										
	RESPONSE:										
	ACPT:										
	RCODE:										
EL	COOK ANNA	PACH	A	2	M	0	99	800 366 4777	61493	06.51	3000
SEN:461376487	CALLED:										
	INFO:										
	RESPONSE:										
	ACPT:										
	RCODE:										
BL	EVERETT M	MYNS	A	1	M	0	99	212 241 7344	11193	14.47	1500
SEN:237522387	CALLED:										
	INFO:										
	RESPONSE:										
	ACPT:										
	RCODE:										
BL	BRINNHAN S	PAUP	A	1	M	0	99	800 543 6393	11193	11.36	2500
SEN:22529046	CALLED:										
	INFO:										
	RESPONSE:										
	ACPT:										
	RCODE:										
BL	SELBY CHV	PAUP	A	1	M	0	99	800 543 6393	2	494 15.53	2500
SEN:052400545	CALLED:										
	INFO:										
	RESPONSE:										
	ACPT:										
	RCODE:										

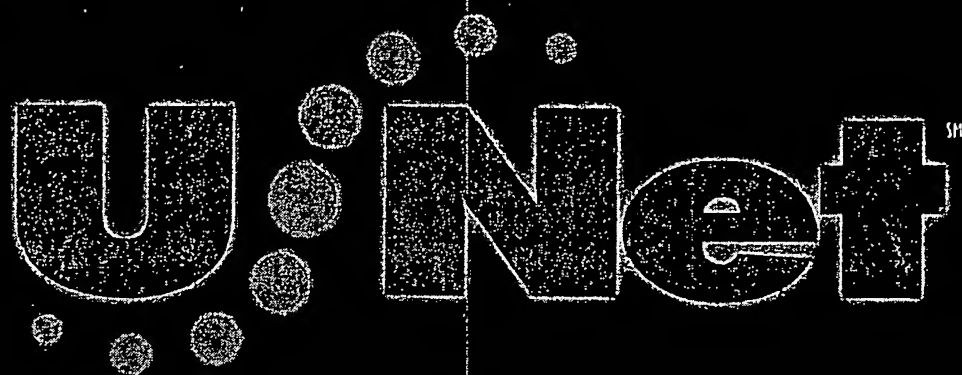
Enter Edit Mode to Request More Lines of Output

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User's Manual



Technology saving lives



Placement

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Introduction to Placement

What is Placement?

Placement refers to the process of adding donors to the national transplant data system, running the donor/recipient matching list, and placing a donated organ(s) with a computer-matched waiting transplant candidate. For example, a member of the procurement team from an Organ Procurement Organization (OPO) enters information into UNetSM about the donor, such as blood type, age, size, and condition at time of death. Once the information is entered, the procurement team member "runs a match" to obtain a waiting list of potential transplant candidates.

From this point, the organ(s) may be allocated to specific transplant candidates in rank order of the match list. Since these functions are primarily the responsibility of OPOs and histocompatibility laboratories, staff members of these organizations are the primary users of the Placement section.

How Placement Works

UNetSM contains a Placement section that allows its users to enter and maintain donor data and run donor/recipient matches. The following functions included in the Placement section:

- Adding a local donor
- Searching for a previously entered donor
- Running organ specific matches
- Recording organ offer information ("PTR")
- Accessing import donor information
- Running matches on living donors
- Adding and running matches for test donors
- Maintaining your OPO's list of donor hospitals
- Entering Crossmatch results
- Recording donor feedback
- Referencing current payback status
- Viewing Completed and Expected PTR data
- Importing PTR data
- Entering monthly referral data

Screen Elements

Menus

The Placement section uses a split screen to help you quickly access the information you wish to view.

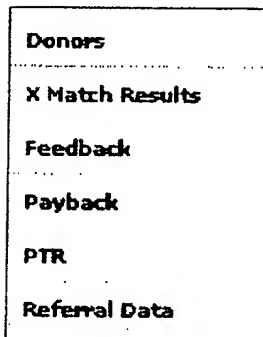
Top Menu Bar

The top menu bar displays the UNOS UNetSM sections. Click on the **Placement** button to navigate through the different sections. The section you have chosen will appear with a white background. The top menu bar also provides access to the Help (question mark), Access (key) and Contact (envelope) features in UNet.

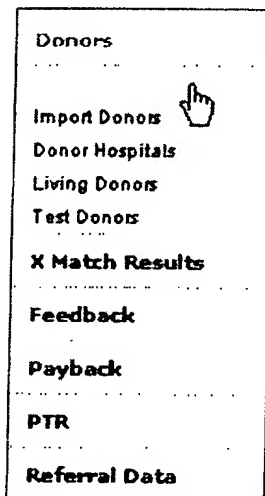


Left Menu

The left side of the split screen displays the topics available in the Placement section.



When you click on the **Donors** button, a submenu of topics displays to the left of the split screen.



Right Window

When you first open Placement, the right window of your screen displays general information about the Placement section.

Page: 432 Group Cd: MAOB Data Cd: MAOB 4370 · John Smith Independent OPO	
Placement	Updated: 11.05.2001
If you need help using the Placement section, please refer to the Placement Online Tutorial.	
Match Run Export Enhancements	
Several enhancements have been made to the match run export process. Match runs for all organ types may now be exported. The screen for exporting match results has been modified to accommodate exporting either full match results or only PTR offer fields. The PTR offers file is exported in tab-delimited format and is smaller than the full match results file. It includes all the fields necessary for obtaining or entering PTR data. The full match results export file is defaulted to the fixed-width file format. However, we have added a checkbox on the export screen to allow you to choose the file in tab-delimited format. We have also added the ctr_px_id (Center's Patient ID) to the end of all the export files. (This field, if completed, is a transplant center-specific ID number.) The length of the PTR offers file or the full match results file may be chosen by indicating the ending classification on the match, or by selecting an ending sequence number.	

After you have made your selection from the left menu, the right window displays your working area. This includes forms, reports, and any other requested information. In this example, the Crossmatch Results Search screen is displayed after clicking the **XMatch Results** button on the left menu.

Donors	Crossmatch Results Search	
X Match Results	Search Criteria	
Feedback	Date Entered:	Between <input type="text"/> And <input type="text"/>
Payback	Donor ID:	<input type="text"/>
PTR		
Referral Data		
<input type="button" value="Search"/> <input type="button" value="Cancel"/> <input type="button" value="Help"/>		

Note: When moving through menus and forms, be sure to use only the application buttons within UNet. Do not use the Internet browser buttons.

For additional information about menus in UNet, see the Menus topic in the help file for each section (General, Waitlist and/or Tied).

Form and List Buttons

The Placement section display several buttons to move you through data completion, or to display a listing of valid choices. Notice that your cursor changes to a hand when it is over a UNetSM button.



Menu Buttons

Menu buttons allow access to functions pertaining to each topic listed. Click the appropriate button to execute the following tasks:

Donors	Display a submenu for local donors, import donors, living donors, test donors and donor hospitals. The Local Cadaver Donor Search Page displays by default.
Local Donors	Display a screen to search for or add cadaveric donors
Import Donors	Display a screen to view imported cadaveric donors and run matches
Donor Hospitals	Display list of, listing an OPO's Donor Hospitals, and provide add and edit functionality of the Donor Hospitals
Living Donors	Display a screen to search for living donors to whom an OPO has been given access to run a match.
Test Donors	Display a screen to add test donors and run test matches.
X Match Results	Display a screen for adding, editing and accessing crossmatch results
Feedback	Display a screen for accessing and editing open donor feedback
Payback	Display the Payback Accounting Search screen for viewing payback debts and credits
PTR	Display a submenu for expected PTR data and importing PTR.
Expected PTR Data	Display a screen for accessing and editing expected and overdue PTR data.
PTR Offer Import	Display a screen for importing PTR Offer data.

Referral Data

Display a screen for entering donor hospital-specific data on donor referrals

Action Buttons

Action buttons allow movement to a different display or form, and/or perform the requested action. Click the appropriate button to execute the following tasks:



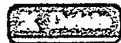
Request that a new donor hospital be added to UNet



Display information about a potential transplant recipient



Close a match run



Found on the Donor Hospitals list, to delete a hospital from an OPO's list. Also found on the Crossmatch Results screen for deleting a crossmatch record.



Export a match run to a text file



Find a specific candidate in the potential recipient list



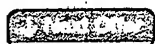
Go to a specific sequence number in the potential recipient list



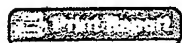
Give access to another OPO to view a donor and run a match



Request a new donor match run



View the next potential recipient without saving the current record



Print the Match Results Report



Restore page periodically until match is complete



Save donor information and run match



View the potential recipient score for organ matches that use allocation points



Save information on a potential recipient record



Save information on the recipient record and go to next offer

Note: For additional information about form/list buttons in UNet, see the *Form/List Buttons* topic in the help file for each section (*General, Waitlist and/or Tied*).

Using the Placement Section

Placement Access

Each UNOS Member has a UNetSM Security Administrator who is responsible for assigning and maintaining security access for each individual user. This process includes:

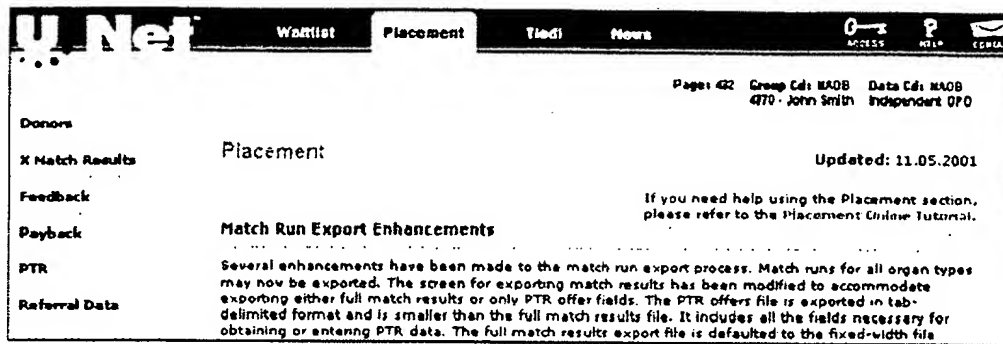
- Assuring that each individual user is registered with the UNOS Membership Department.
- Creating a UNet Security Profile for the individual user, which includes the user's login ID, password and access control.
- Assigning one or more Security Groups to the user.

Your UNet display depends upon your Security Profile. Each Security Profile allows access to specific parts of the UNet system and limits or restricts the user's access to certain applications. For example, if a user's responsibilities include adding donors to UNet, his/her access should include access to that part of Placement.

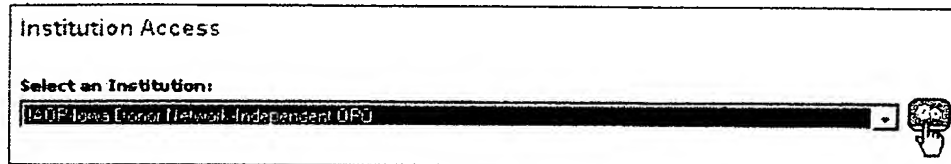
The UNet menu does not display restricted areas as a choice. In some cases, the user can access an application, but certain selections, actions, or information are restricted and not displayed.

Beginning a Session in Placement

1. From any screen in UNetSM, click on the **Placement** button located on the top menu bar as displayed below. The main screen will display the left menu and right window. The Data Cd displayed at the top-right of the screen is the center with which you are currently logged in. It defaults to the last institution you accessed in this section.



2. If you would like to change the institution, click the **Access** button on the top menu bar. Then select the desired institution/program from the drop-down menu and click the **Go** button.



Donor Hospitals

Accessing the Donor Hospital List

When adding a donor to UNetSM, the donor hospital is a required field. A list of donor hospitals associated with your OPO is available in the Donor Hospitals section.

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. From the Placement menu page, click on the **Donors** button on the left menu. Then click the **Donor Hospitals** button. The Donor Hospitals list is displayed for your OPO.

Donor Hospitals for MAOB

Provider # ▼	Name ▼	City	State	Status
220077	AAA BAYSTATE MED CENTER	SPRINGFIELD	MA	Active
220128	ADDISON GILBERT HOSP	GLOUCESTER	MA	Inactive
220930	AMERICAN RED CROSS BLOOD SVCS	DEDHAM	MA	Inactive
010145	AMI WEST ALABAMA GENERAL HOSP	NORTHPORT	AL	Active
220029	ANA JACQUES HOSP	NEWBURYPORT	MA	Active

Note: You may re-sort your list by clicking on any column designated with a red drop-down arrow. The hospital may be re-sorted by provider number and name.

3. To access information about a hospital listed, click the hospital's **Provider #**. The Donor Hospital information page will display.

Donor Hospital

Hospital Information

OPO: 22P001 - MAOB - New England Organ Bank
 Donor Hospital: 220077 - BAYSTATE MED CENTER

AAA BAYSTATE MED CENTER

Time Zone: **EASTERN** ▼


Longitude: 72.6085 degrees West Latitude: 42.1213 degrees North

Status: ☒ Active ☐ Inactive

Update **Back** **Cancel**

4. You may modify the name of a donor hospital and/or change the time zone information.
5. Click the **Update** button to save any changes, or click the **Back** button to return to the Donor Hospitals list.

Adding/Deleting a Donor Hospital

1. Access the Donor Hospital list. (See *Accessing the Donor Hospital List*)
2. Click on the  button at the top of the page. The Provider Search screen is displayed.

Provider Search

Search Criteria

Number:

Name:

City:

State:

3. Enter your search criteria and click **Continue**. For steps on adding a new donor hospital to UNetSM, see *Adding a New Provider to UNet*.

The Donor Hospitals page is displayed with results from the search.

Donor Hospitals

Search Criteria:

Prov State = AZ

Results from search. If needed, choose a hospital to add.

032542 - ARCADIA DIALYSIS CTR, PHOENIX, AZ

03028E - ARIZONA STATE ELKS ASSN HOSP, TUCSON, AZ

03029E - BAGDAD HOSP, BAGDAD, AZ

030063 - BAPTIST MEDICAL CTR-SCOTTSDALE, SCOTTSDALE, AZ

Currently assigned hospitals. If needed, choose a hospital to delete.

220077 - AAA BAYSTATE MED CENTER

220128 - ADDISON GILBERT HOSP

220830 - AMERICAN RED CROSS BLOOD SVCS

010145 - AMI WEST ALABAMA GENERAL HOSP

From this page you may:

- Select a hospital to add from the search results (at the top of the page). Click the **Add** button at the bottom of the page. The following message is displayed:

Successfully added donor hospital record.


- Select a hospital to delete from the list currently assigned to your center at the bottom of the

page (the bottom area on the page). Click the **Delete** button. The following message is displayed:

Successfully deleted donor hospital record.

Adding a New Provider to UNetSM

If a donor hospital is not listed in UNetSM, you may request that it be added.

1. Access the Donor Hospital list. (See *Accessing the Donor Hospital List*)
2. Click the  button at the top of the page. The Provider Search screen is displayed.

Provider Search


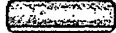

Search Criteria

Number:

Name:

City:

State:

3. Enter the provider number only and click **Continue**. The following Donor Hospitals screen will display:


Donor Hospitals

Search Criteria:

Prov Num = 121212





No providers returned.

Add New Provider - This is to add Non-UNOS members ONLY.
This is to be used when searching only by entire provider number. New UNOS requests for TXCs, Labs, and OPOs are to be handled through UNOS Membership Department.



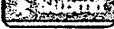
Currently assigned hospitals. If needed, choose a hospital to delete.

012526 - ALABAMA DIALYSIS SERVICES	▲
010145 - AMI WEST ALABAMA GENERAL HOSP	
220029 - ANA JACQUES HOSP	
220003 - ATHOL MEMORIAL HOSP	▼

4. Click the **Add New** button. You will be asked to confirm that the provider number is correct before continuing, because you will not be able to change that number on the following page. More than one hospital can be listed with the same provider number. The Request to Add New Provider page will display.

Request to Add New Provider	
This is to add Non-UNOS members ONLY.	
New UNOS requests for TXCs, Labs, and OPOs are to be handled through UNOS membership department.	
Use the form below to send your request for a new provider to be added.	
Requestor Information	
Name:	John Smith
Institution:	MAOB - OP1
Phone:	R <input type="text"/> - <input type="text"/> - <input type="text"/>
Fax:	<input type="text"/> - <input type="text"/> - <input type="text"/>
E-mail:	<input type="text"/>

5. After completing the form, click the  button, and your request will be forwarded to the UNOS Help Desk to be processed.

Note: This request form is to add Non-UNOS members only. Contact the UNOS Membership Department to have UNOS transplant centers, labs or OPOs added.

Inactivating a Donor Hospital




A donor hospital that is associated with one or more donors in UNetSM cannot be deleted from the list. However, you may inactivate the donor hospital if it is no longer used, so that the name will no longer appear on future Donor Referral lists or as a choice when adding a donor.

1. Access the Donor Hospital list. (See *Accessing the Donor Hospital List*)
2. Click the **Provider #** of the center you wish to inactivate.

Provider # ▼	Name ▼	City	State	Status
	AAA BAYSTATE MED CENTER	SPRINGFIELD	MA	Active
220128	ADDISON GILBERT HOSP	GLOUCESTER	MA	Inactive


The Donor Hospital Information page is displayed.

Donor Hospital
Hospital Information
 OPO: 22P001 - MAOB - New England Organ Bank
 Donor Hospital: 220077 - BAYSTATE MED CENTER
 AAA BAYSTATE MED CENTER
 Time Zone: EASTERN ▼
 Longitude: 72.6085 degrees West Latitude: 42.1213 degrees North
 Status: ☒ Active ☐ Inactive

3. Click on the **Inactive** button at the bottom of the page.
4. Click on the **Update** button to save the change. When you return to the Donor Hospital list page, note that the Status column on the right side now displays *Inactive* for this hospital. Inactive hospitals will not display on future Donor Hospital Referral Data lists or as a choice in the Donor Hospital drop-down box on the donor entry page.

Donor Hospitals for MAOB
Successfully updated donor hospital record.



Provider # ▼	Name ▼	City	State	Status
	AAA BAYSTATE MED CENTER	SPRINGFIELD	MA	Inactive

Donors

Accessing an Existing Local Donor

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Click on the **Donors** button on the left menu. The Local Cadaver Donor Search page is displayed. Any donors added within the last 5 days will also display on the page, to assist in preventing duplicate donor entry.

Local Cadaver Donor Search

Search Criteria

Add Date: Between and

Donor Id:

Donor Hospital:

Last Name:

Age Range: Between and

ABO:

Donors added within the last 5 days

Donor ID	Name	Age	Gender	ABO
OJM001	Robinson, Test	35 yrs	Female	A


3. If the donor appears at the bottom of the screen, click on the **Donor ID** to display the donor record. Otherwise, enter any combination of search criteria and click on the **Search** button at the bottom of the page. The Local Cadaver Donors list is displayed.

Local Cadaver Donors

Donor ID	Name	Age	Gender	ABO	Add Date
OJM001	Robinson, Test	35 yrs	Female	A	10/13/2001 11:04
AD001	Vader, Darth	70 yrs	Male	A	08/23/2001 00:47

4. Select a Local Donor from the list and click on the **Donor ID**. The Local Cadaver Donor page is displayed for the donor you selected.

Local Cadaver Donor



UNOS ID Information for Donor ID: OJM001

OPO: 22P001 - MAOB - New England Organ Bank
Donor Hospital: 220029 - ANA JACQUES HOSP
Donor Name: Robinson, Test
Donor Feedback: Status OPEN

Match Run Information

ABO: A	Gender: Female
Age: 35 Years	Height: 5 ft 0 in/152.4 cm
DOB: 05/19/2001	Weight: 125 lbs/56.699 kg

Viewing and Editing Donor Information

- To edit the donor information, click the **Edit** button at the top of the page. Enter or change information and then click on the **Update** button at the top or bottom of the page.
- To display existing match results for the donor, use the scroll bar on the right side of the screen to navigate to the bottom of the page. Click an organ noted as complete in the list of Match Runs. The match list will display on the screen.
- To view or complete Donor Feedback, click on **Donor Feedback**, which appears beneath the donor name at the top of the form. The Donor Feedback status is noted on the form as either **OPEN** or **CLOSED**.

Adding a Local Donor

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Click on the **Donors** button on the left menu. The Local Cadaver Donor Search page is displayed. Any donors added within the last 5 days will also display on the page, to assist in preventing duplicate donor entry.

Local Cadaver Donor Search

Search Criteria

Add Date: Between and

Donor Id:

Donor Hospital:

Last Name:

Age Range: Between and

ABO:

Donors added within the last 5 days

Donor ID	Name	Age	Gender	ABO
03H001	Robinson, Test	35 yrs	Female	A

3. Click on the **Add** button at the bottom of the page. The Cadaver Donor Add form is displayed.

Cadaver Donor Add

UNOS ID Information

OPD R 22P001 - MAOB - New England Organ Bank

Donor Hospital:

Last Name: First Name:

Ethnicity:

Race: ☐ White
☐ Black or African American
☐ American Indian/Alaskan Native
☐ Asian
☐ Native Hawaiian or Other Pacific Islander
☐ Mid-east/Arabian
☐ Indian Sub-continent

4. To quickly obtain a donor ID, complete only the required fields of Donor Hospital, Name, Ethnicity and Race. If you have additional donor information, proceed with completing the applicable fields.
5. Click on the **Save** button at the top or bottom of the page.

Note: You may save the record and run a match simultaneously by clicking on the Run Match button. See Running a Match for steps on running a match and placing organs.

6. The Local Cadaver Donor Search page reappears. A message is displayed that the donor record has been successfully added, along with the donor name and the donor ID.

Local Cadaver Donor Search

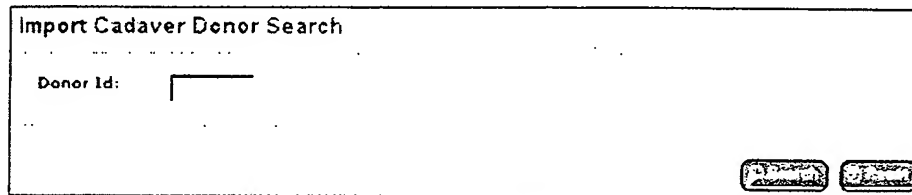
Successfully added donor Robinson, TestDonor ID: OJM001

Accessing Imported Donors

When an OPO needs to run a match for a donor organ that was originally recovered by another OPO, the receiving OPO must first be given access to the donor by the originating OPO.

To access the imported donor record:

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Click on the **Donors** button on the left menu. Then the **Import Donors** button. The Import Cadaver Donor Search screen is displayed.



3. Enter the **Donor ID** and click on the **Search** button.
4. The Cadaver Donor Page is displayed for the donor you specified. From the donor record, you may run a match and place the organ as described in the lesson for *Running a Match*. The match run is only accessible to the OPO who runs it.

Note: If you are unable to access the import donor record, contact the originating OPO to verify that *Import Access has been given*. (See *Giving Import Access to Another OPO for more information*)

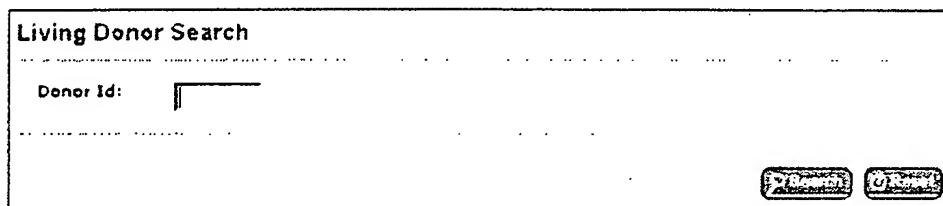
Accessing a Living Donor

In cases of anonymous living donor transplants, the work-up transplant center must designate in Tiedi® on the living donor record that the OPO can run a match on that donor.

Once the transplant center has given access, you may open the living donor record by taking the following steps:

1. Begin your Placement session. (See *Beginning a Session in Placement*)

2. Click on the **Donors** button on the left menu. Then click the **Living Donors** button. The Living Donor Search page is displayed.



Living Donor Search

Donor Id:

3. Enter the Donor ID and click on the **Search** button.
4. The Living Donor record will display for the donor you specified. You may run a match and place the organ as described in the *Running a Match* lesson.

Test Donors

Adding a Test Donor

The Test Donor function is available for OPOs to use in training their staff, and may also be used to locate where local transplant candidates would appear on a match list, given a set of test data.

To add a test donor:

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Click on the **Donors** button on the left menu. Then click the **Test Donors** button. The Test Cadaver Donor Search page is displayed.

Test Cadaver Donor Search

Search Criteria

Add Date: Between and

Donor Id:

Donor Hospital:

Last Name:

Age Range: Between and

ABO:

Search Add Reset

4. Click on the **Add** button. The Test Cadaver Donor Add page will display.

Test Cadaver Donor Add

UNOS ID Information

OPO R 22P001 - MAOB - New England Organ Bank

Donor Hospital:

Last Name: First Name

Ethnicity: R

Race: R

☐ White

☐ Black or African American

5. Complete all the required fields (Donor Hospital, Name, Ethnicity and Race) and any optional information.

Note: Weight and height are not required for test donors.

6. Click on the **Save** button. You may save the record and run a match simultaneously by clicking on the **Run Match** button.
7. The Test Donor Search page will reappear, with a message that the donor record has been successfully added, along with the donor ID:

Successfully added donor Smith, Johan Donor ID: 200059

Running a Test Match

The Test Donor function is available for OPOs to use in training their staff, and may also be used to locate where local transplant candidates would appear on a match list, given a set of test data.

To access a test donor and run a match:

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Click on the **Donors** button on the left menu. Then click on the **Test Donors** button. The Test Cadaver Search page is displayed.

Test Cadaver Donor Search

Search Criteria

Add Date: Between and

Donor Id:

Donor Hospital:

Last Name:

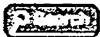


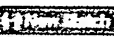
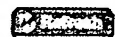
Age Range: Between and

ABO:

3. Enter your search criteria and click on the **Search** button. A list of test donors meeting your criteria will display.

Test Cadaver Donors					
Donor ID	Name	Age	Gender	ABO	Add Date
200022	A test, really	30 yrs	Female	A	07/20/2001 14:26

4. Click on the **Donor ID** to display the Test Local Cadaver Donor page.

Test Local Cadaver Donor	
    	
UNOS ID Information for Donor ID: 200022	
OPO: 22P001 - MAOB - New England Organ Bank Donor Hospital: 220029 - ANA JACQUES HOSP Donor Name: A test, really	
Match Run Information	
ABO: A Age: 30 Years DOB: 01/01/1971	Gender: Female Height: 5 ft 5 in/165.1 cm Weight: 155 lbs/70.3068 kg
Additional Match Run Information	
HCV Antibody: Negative Hepatitis B Core Antibody: Negative HLA: A:10 A:3 B:12 B:12 DR:6 DR:7 Previous Gastrointestinal Disease: No	

5. Click on the **New Match** button to enter test match run information.


Match Runs Requested		
<input type="checkbox"/> Kidney	<input type="checkbox"/> Heart	<input type="checkbox"/> Liver
<input type="checkbox"/> Kidney/Pancreas	<input type="checkbox"/> Heart/Lung	<input type="checkbox"/> Intestine
<input type="checkbox"/> Pancreas	<input type="checkbox"/> Lung	

6. Select the organ-specific match runs requested, as well as any additional match run information.

Click on the  button.

Note: Height and weight are not required to run a test match.

7. The Match Run page will refresh with the box at the top noting the matches as **Organ Type (Queued)** or **Organ Type (Running)**.

8. Click on the  button at the top or bottom of the page periodically until the match has completed.

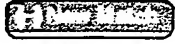
9. Click on **Organ Type (Completed)** to view the Potential Recipient List.

10. When reviewing a test match, note that candidates from outside of your OPO are blinded by the system. Their information will appear as asterisks. This blinding provides patient and center confidentiality.

Note: To view the Potential Recipient List at a later date, access the Test Donor as before, and select the applicable Match Run at the bottom of the Test Local Cadaver Donor page.


Match Runs

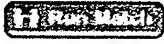

Running a Match

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Access a donor record as explained in *Accessing an Existing Local Donor*. (The steps for running a match are the same for local, import, living and test donors).
3. Click on the  button at the top or bottom of the page.
4. Review and edit any information.
5. The organ specific match choices are found in the Match Runs Requested section. Check the type of match needed.

Match Runs Requested		
<input type="checkbox"/> Kidney	<input type="checkbox"/> Heart	<input type="checkbox"/> Liver
<input type="checkbox"/> Kidney/Pancreas	<input type="checkbox"/> Heart/Lung	<input type="checkbox"/> Intestine
<input type="checkbox"/> Pancreas	<input type="checkbox"/> Lung	

Note: For entered Crossmatch results to be considered in the kidney or kidney/pancreas match process, you must designate the tray or trays to be included. This can be done by choosing a tray or trays from the field labeled Select Crossmatch results in the middle of the page. Multiple trays may be chosen by holding down the Ctrl key on the keyboard while using the mouse to highlight the trays to be considered.

Is there time for a Preliminary Crossmatch?	<input type="radio"/> YES	<input type="radio"/> NO
Select Crossmatch results:		
	ALOB-01-05/26/2000	

6. Click on the  button at the top or bottom of the Cadaver Donor page.
7. The Match Run page will refresh with the box at the top noting the matches as **Organ Type (Queued)** or **Organ Type (Running)**.
8. Click on the  button at the top or bottom of the page periodically until the match has completed.
9. Click on the **Organ Type (Completed)** to view the Potential Recipient List.

Note: To view the Potential Recipient List of a match that has been previously run, access the Local Donor as before, and select the applicable Match Run at the bottom of the Local Cadaver Donor page.

10. The Potential Recipient List will display 20 records per page. Each candidate on the list is identified by match sequence number, center code, SSN, name and a contact phone number.

Seq #	Hosp	SSN	Name	Contact #	Refusal Code	Organ Accepted
13911	ALUA-TX1	111-22-3334	Aatest, Bob	(800)252-3677		

On a Pancreas Match Run, if the 4-letter Center Code has parentheses around it, that center will accept a facilitated pancreas. Click on the SSN to view information about the potential recipient and record organ offer data.

12934	(ALUU-TX1)	111-22-3333	Doe, Jane	(800)252-9000
-------	------------	-------------	-----------	---------------

11. To view the next 20 records, click on the arrow button at the bottom of the page.



Beginning of List



Previous 20
Records




Next 20
Records



End of
List

Finding a Specific Candidate on the Match Run

To find a specific candidate on the match run, or to find a candidate who was screened off the list, take the following steps:

1. Access a match run. (See *Running a Match*)
2. Click on the  button at the top of the page.

Find a Kidney Candidate

Search Criteria

Tx Center: R

Candidate SSN:


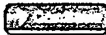

Last Name:

First Name:

Records Per Page:


Include: ☒ Located on Match ☐ Screened off Match ☐ Both

Sort Order: ☒ Seq# ☐ Name ☐ Reason

3. Enter a transplant center and any other search criteria.
4. Click on the **Continue** button. The Find a Candidate Search Results page will display.

Find a Candidate Search Results



Match Information

Donor ID: OJM001 Donor Name: Robinson, Test

Match Run: 1 Match ID: 98027

Name	SSN	Seq #	Reason	Status	Organ
------	-----	-------	--------	--------	-------

5. Search results will include either a sequence number of the potential recipient on the list, or the reason code for why the potential recipient was screened off the list, dependent on the criteria entered.
6. By clicking on a candidate's **Reason** code, you may display a snapshot of their record at the time of the match run.

Note: The  button at the bottom-right of the search results screen provides a list of the reason codes.

Going to a Specific Sequence Number on the Match Run

To go directly to a specific sequence number on a match run, take the following steps:

1. Access a match run. (See *Running a Match*)
2. Click in the **Go to Candidate Sequence Number** field, and type the sequence number you wish to view of the candidate.

Go to Candidate Sequence Number : 15	
--------------------------------------	---


3. Click the **Go To** button. The Potential Recipient List will refresh to display the sequence number of the candidate you designated.

Seq#	Hosp	SSN	Name	Contact #	Refusal Code	Organ Accepted
15	MABS-TX1	111-12-1241	SMITH, WILLIAM	(800)874-5215		




Giving Import Access to Another OPO

When an OPO needs to run a match for a donor organ that was originally recovered by another OPO, the originating OPO must first give access to the donor record.

1. Access a match run. (See *Running a Match*)

2. Click on the  button at the top of the match. A list of all OPOs will display.

Import Access



Select the OPO(s) you want to give import access to:

☐

ALOB - Alabama Organ Center

☐

AROR - Arkansas Reg. Organ Recovery Agency

☐

AZOB - Donor Network of Arizona

☐

CADN - CA Transplant Donor Network

☐

CAGS - Golden State Donor Services

☐

CAOP - OneLegacy

☐

CASD - Lifesharing Community Organ Donation

☐

CORS - Donor Alliance


☐


3. Check off the OPO(s) who need access to the donor record.
4. Click on the **Update** button to save the information and return to the Potential Recipient List. The designated OPOs will now be able to access the donor record and run matches.
5. A message will display that import access has successfully been given. However, the designated OPO will not be able to view any matches that have already been run by the originating OPO.

Note: *Import access may be taken away by unchecking the box(es) under Import Access.*

Viewing Candidate Information

Additional candidate information is available on patients who are affiliated with the OPO running the match.


1. Access a match run. (See *Running a Match*)
2. Click on a candidate's **SSN** to view the Potential Recipient Information page. The donor will display at the top of the page. Information about the potential recipient is displayed below the donor information to assist you in making organ offers to the candidates on the list.
3. Click on the  button at the top of the screen. This will display the Potential Recipient page, which includes provider, demographic and clinical information. It also includes the minimum acceptance criteria and unacceptable antigens for the candidate.

Potential Kidney Recipient	
	
Provider Information	
Transplant Center:	220031 - MABU - Boston Medical Center
24 Hour Contact Phone Number:	800-446-6362

4. Click on the **Back** button to return to the match results.

Viewing Potential Recipient Score Breakdown

A candidate's score breakdown is available to determine why the candidate is located at a specific sequence number on the match. The ability to view the Potential Recipient Score is only available for organ matches that use allocation points, e.g. Kidney, Liver, etc.

1. Access a match run. (See *Running a Match*)
2. Click on a candidate's **SSN** to view the Potential Recipient Information page.
3. Click on the  button at the top of the screen. This will display the Potential Recipient Score Breakdown, which includes donor and potential recipient information and the point breakdown for the candidate.

Potential Recipient Score Breakdown

Donor Information for Donor ID: OGS002

10719, 1002

Match Run #: 3

Match Submit Date: 07/19/2001 13:43:15

HLA: A: 0 A: 0 B: 0

Match ID: 72028

ABO: O

B: 0 DR: 0 DR: 0

4. Click on the  button to return to the match results.



Entering PTR Information

Entering Organ Offer (PTR) Data

1. Access the match run used to allocate the organ. (See *Running a Match*)
2. Click on the **SSN** to view information about the potential recipient and to record organ offer data.
3. When a placement attempt has been made, the following information should be entered for every candidate who was offered the organ.
 - A value for **Accept** - Yes, No, or Pending
 - If Yes or No, a **Respond Date** (in MM/DD/YYYY format) and military **Time** (in HH:MM format). *Date is required, but Time is not.*
 - If Yes or No, the name of the **Recipient Center Contact**. *You must fill in first or last name, but both are not required.*
 - If the organ was refused, the **Primary Refusal Code** from the drop-down list
 - If the organ was accepted, the organ type accepted

Note: If 998 is chosen as the refusal code, you must complete the *Specify Other* field.

Placement Attempt	
Accept: <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Pending	
Respond Date:	Time:
Recipient Center Contact	
First Name:	Last Name:
Refusal Code	
998 Refusal Code - Specify Other	

4. Click the  button at the top or bottom of the page to save the record -OR- click the  button to save the information and go to the next potential recipient on the list.

The  button will return you to the Potential Recipient List without saving the current record.

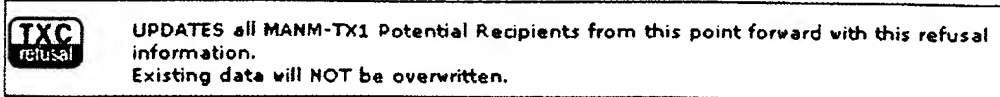
The  button takes you to the next potential recipient without saving the current record.

For helpful tips on entering potential recipient information, see *Tips for Entering PTR Data*.

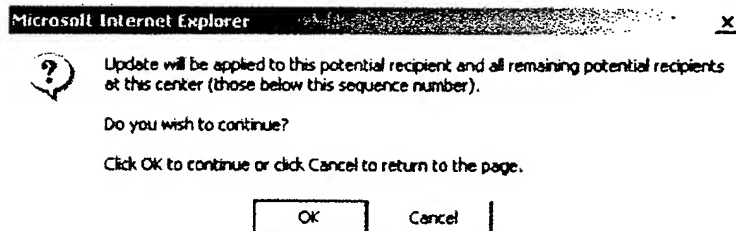
Recording a TXC Refusal

To record the same refusal reason for all of a transplant center's candidates:

1. Open the record of a center's first potential recipient on the list, and complete the required fields with the refusal information. (See *Entering Organ Offer (PTR) Data* and *Tips for Entering PTR Data*.)
2. Click on the **TXC Refusal** button found toward the bottom of the Potential Recipient Information screen.



3. A warning message will appear.



4. Click **OK** to continue with the update. The current patient record and all subsequent patient records for the same transplant center will be updated with the same refusal information.
5. A message will display that the TXC Refusal was successful.



Note: This action will not overwrite any existing data. If refusal information already exists in a record, other than the record you are currently entering, it will not be affected when the TXC button is used. If a mistake is made when pressing the TXC Refusal button, the action CANNOT be undone. Each entry must be corrected manually.


Recording a Range Refusal

To record the same refusal code for a range of records:

1. Open the record of a potential recipient on the list, and complete the required fields with the refusal information. (See *Entering Organ Offer (PTR) Data* and *Tips for Entering PTR Data*.)


Note: This option can only be used with OPO-specific refusal codes. The accepted codes are 906, 991-996 and 998.

2. Note the sequence number through which you would like to apply the same refusal information. Enter this number in the **Ending Sequence Number** field. This number must be after the current record's sequence number, and cannot be greater than the last sequence number on the match.

	UPDATES all Potential Recipients from this point forward, up to and including the indicated ending sequence number regardless of center with this refusal information. An OPO related refusal code is required. Existing data will NOT be overwritten.
<input type="text"/>	Ending Sequence Number

3. Click on the Range Refusal button. A warning message will appear.

Microsoft Internet Explorer

 Update will be applied to this potential recipient and potential recipients through Seq# 4.
Do you wish to continue?
Click OK to continue or click Cancel to return to the page.

4. Click OK to continue. A message will display that the Range Refusal was successful.

Kidney Donor / Potential Recipient Information
Range Refusal Successful

Note: This action will not overwrite any existing data. If refusal information already exists in a record, it will not be changed when the Range Refusal button is used. If a mistake is made when pressing the Range Refusal button, the action CANNOT be undone. Each entry must be corrected manually.

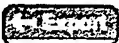
Tips for Entering PTR Information

Entering PTR information can be accomplished quickly with the use of your keyboard. Here are a few pointers to help:

- Begin in the **Accept: Yes** field in the Placement Attempt section. Simply press the SPACEBAR on your keyboard to mark the **Yes** field.
- If the answer for Accept is **No**, press the RIGHT ARROW on your keyboard. Press the right arrow once more to enter an answer of **Pending**.
- Press the TAB button on your keyboard to advance to the next field.
- When you reach the **Refusal Code** field, you have several options.
 - You may type the refusal code, and the closest match will appear. An example is 921 for Donor Quality. If a mistake is made, the DELETE key will clear all previous keystrokes.
 - You may also use the up arrow or down arrow to scroll through the list of choices.
 - The HOME key will take you to the top of the list. The END key will take you to the end of the list. The PAGE UP and PAGE DOWN keys will skip several choices at a time.
- To TAB in the reverse order, hold down the SHIFT key as you press TAB.
- You may use the TAB button to navigate through the remaining buttons/fields on the page (e.g. Range Refusal, Update, Next Offer). Press the ENTER key on your keyboard to select the button(s) you wish to choose.

Exporting PTR Data

Full match results or PTR offers may be exported for all organ types in a fixed-width or tab-delimited text file. The PTR offers file may be opened in a spreadsheet so that data can be entered for the candidates on the match. This data can then be imported back into UNetSM following the steps in PTR Offer Import.

1. Access a match run. (See *Running a Match*)
2. Click on the  button at the top or bottom of the page. A Match Results Export screen will display.

Match Results Export

Match Information

Donor ID : OJY004	Match ID : 98200	Maximum Sequence Number : 412
Donor : donor, maob test	Organ : Pancreas	Close Sequence Number :

Export Information

Export type : ☒ Full Match Results ☐ PTR Offers



Tab delimited ☐

Include results through
Classification :

- OR -

Sequence Number :

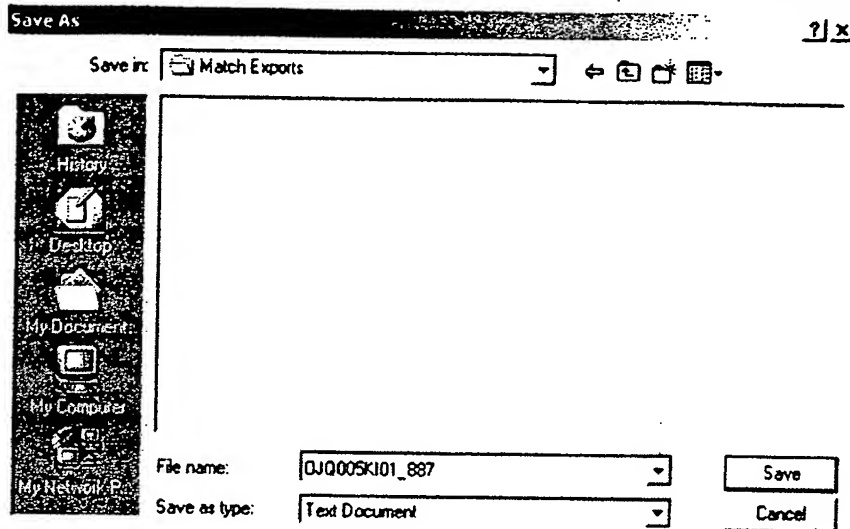
Maximum Sequence Number for Classification appears in parenthesis

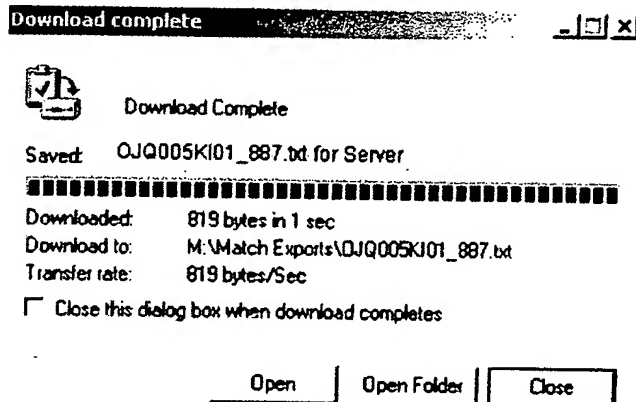
3. Select either **Full Match Results** or **PTR Offers** from the Export type field. The PTR offers file is exported in tab-delimited format and is smaller than the full match results file. It includes all the fields necessary for obtaining or entering PTR data. The full match results export file is defaulted to the fixed-width file format, but may be changed to tab-delimited.
4. The length of the PTR offers file or the full match results file is chosen by indicating the ending classification on the match, or by selecting an ending sequence number.
5. Click the **Export** button. When the export request is complete, a link similar to the following will appear on the bottom of the screen:

Right-click and Save Target As... to download OJY005KI01T_001.TXT

6. Right click on the link and choose **Save Target As** from the menu. The **Save as** box appears.




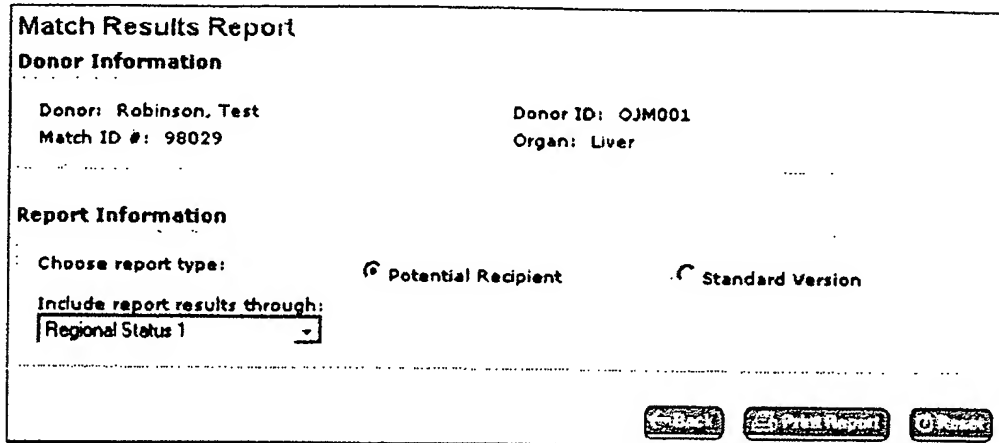
7. Designate the location or directory to which you would like the file saved, and click the **Save** button.
8. A completed dialog box will display from which you may select **Open** (to view the file), **Open Folder** (to open the folder containing the file) or **Close** (to close the dialog box).



9. The corresponding file layouts for PTR Offers and Full Match Results are found in the News section of UNet.

Printing a Potential Recipient List

1. Access a match run. (See *Running a Match*)
2. Click on the  button. The Match Results Report screen will display.



Match Results Report




Donor Information

Donor: Robinson, Test Donor ID: OJM001
Match ID #: 98029 Organ: Liver

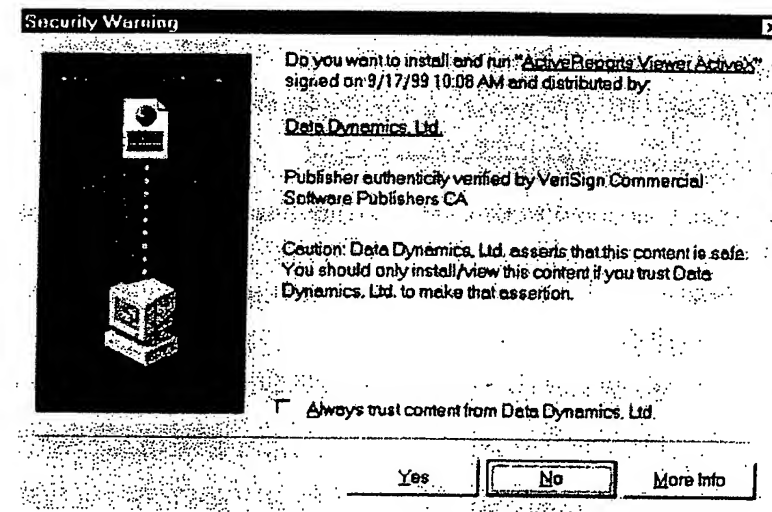
Report Information

Choose report type: ☒ Potential Recipient ☐ Standard Version

Include report results through:

3. Choose the type of report to be printed, *Potential Recipient* version or *Standard* version. The Potential Recipient version includes detailed candidate information and space to record organ offer information - fewer candidates will print on a page. The Standard version lists candidate information only - more candidates will print on a page.
4. Use the drop-down menu to choose the allocation group (e.g. Common OPO List, Regional List) to include as the last section on the printed report.
5. Click the **Print Report** button.
6. The first time you do this, you will be prompted to load an Active Reports Viewer.



7. Click **Yes** to install and run ActiveX.

8. A message will display as the report is processing.

Your Liver Match Results Report is processing, thank you for waiting...

9. The Match Results Report will be displayed on the screen in the format requested.

Liver Match Results Report

UNOS LI
Potential
Adult Donor

Donor Id: OJM001 Run Number: 2 Match Id: 98029

Provider Information

OPO: 22P001 - MAOB - New England Organ Bank

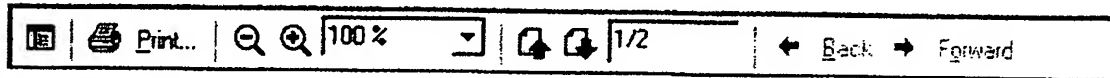
Donor Hospital: 220035 - ATLANTICARE UNION HOSPITAL

Demographic Information

Name: Robinson, Test

10. Click on the **Print** icon found at the top of the Active Reports Viewer frame to set your printing properties and print the report.

ActiveX Toolbar



Zoom Out

Press the button one or more times to display more of the report on the screen.

Zoom In

Press the button one or more times to show areas of the report in greater detail.

Page Navigation

Previous Page takes you back one page at a time.

Next Page takes you forward one page at a time.

Page Numbers displays the current page followed by the total pages in the report. In the example above, the user is on page 1 of a total of 2 pages. The desired page number may also be manually entered in this field.

Hand Cursor



To see parts of a page not displaying on the screen, click anywhere on the page and drag your mouse in any direction. (You may also use the scroll bars at the right and bottom of the screen.)

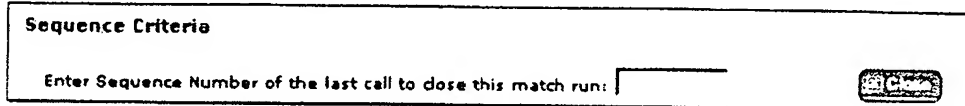
Clinical Information	
ABO: A	
Height (cm): 178	Height (in): 70
Weight (kg): 68	Weight (lbs): 150
HCV Antibody: Negative	

Note the way the hand cursor "grabs" the page as you click and drag your mouse in any direction.

Closing a Match Run

After the last offer has been made on a Potential Recipient List, the Match Run must be closed. By closing a match you are indicating that the match is complete as recorded.

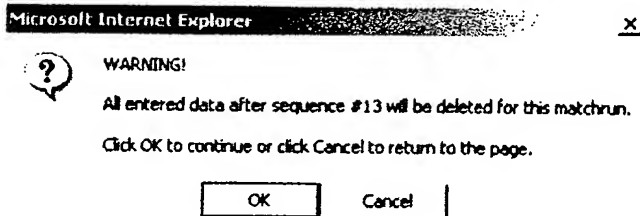
1. Access a match run. (See *Running a Match*)
2. Note the sequence number of the potential recipient for whom the last call was made.
3. Enter the sequence number of the last call in the field shown below, and click on the **Close** button.



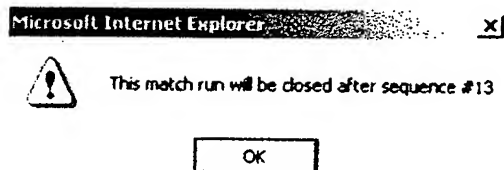
Sequence Criteria

Enter Sequence Number of the last call to close this match run: **Close**

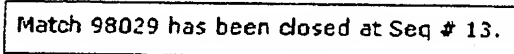
3. A dialog box will display, asking for verification of this action. Click **OK** to proceed with closing the match run.



4. A second message will appear, stating that the match run will be closed at the designated sequence number. Click **OK**.



5. A message will display at the top of the screen that the match run was successfully closed at the designated sequence number.



If you find that you need to change the match run close number, you may change it to a different sequence number. Any records after the close number will be removed.

Several factors affect how this action can be performed:

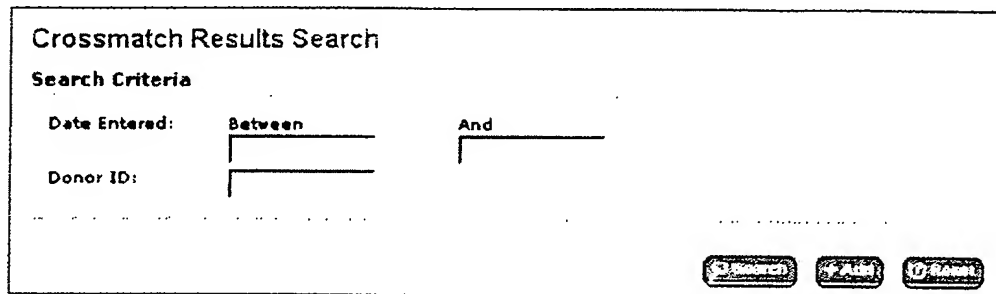
- If any records have a status of Yes AFTER the last call sequence number, a member will not be able to close the match run at that number. Those records must be included.

- If any records have a status of Pending BEFORE the last call sequence number, a member will not be able to close the match run at that number. Those records need to be updated to Yes or No.
- If the Organ Center has entered information in any of the records listed AFTER the last call sequence number, a member will not be able to close the match run at that number. Those records must be included.

Crossmatch Results

Adding Crossmatch Results

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Click on the **X Match Results** button on the left menu. The Crossmatch Results Search screen will display.



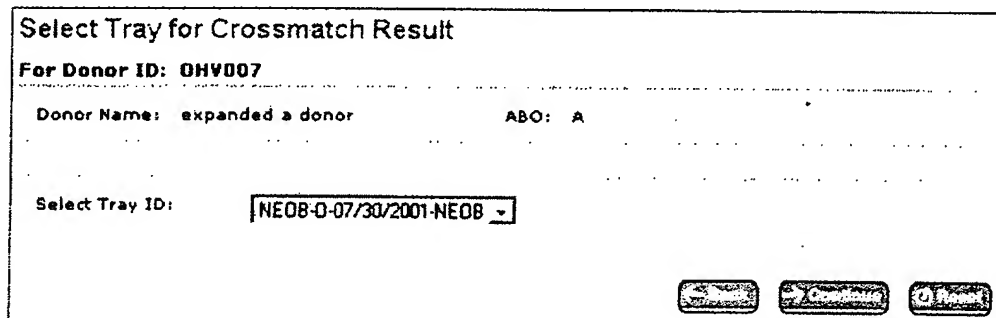
Crossmatch Results Search

Search Criteria

Date Entered: Between And

Donor ID:

3. Enter a Donor ID number and click on the **Add** button. A Select Tray for Crossmatch Result page is displayed.



Select Tray for Crossmatch Result

For Donor ID: OHV007

Donor Name: expanded a donor ABO: A

Select Tray ID:

4. Choose a tray from the drop-down box to which Crossmatch results will be entered.

5. Click on the **Continue** button. The Crossmatch Results page will appear. The Donor Name, Tray Name and ID will be displayed at the top of the page.

Crossmatch Results

For Donor ID: ohv007

Donor Name: expanded a donor Tray Name: NEOB-O Tray ID: 597	ABO: A Tray Date: 07/30/2001 Lab: NEOB
--	---

SSN	Center	ABO Name	Row	Result	Peak PRA	Current PRA	Serum (month/year)
111-22-3333	MANM		1A/1	<input type="text" value="0"/>	80	50	01/2001
100-11-1111	MANM		1B/2	<input type="text" value="0"/>	85	40	01/2001
456-12-3456	MANM	A Candidate, Liver	1C/3	<input type="text" value="0"/>			01/2001
456-12-3456	MANM	A Candidate, Liver	1D/4	<input type="text" value="0"/>			01/2001
111-22-3233	MANM		1E/5	<input type="text" value="0"/>	12	2	01/2001
			1F/6	Empty			

6. Enter the Crossmatch results in the **Result** fields. Results can be entered either by using a mouse to choose the number designated result for each patient, or results can be manually entered using the tab key to navigate to the next field.
7. Once the results have been entered on the tray, click on the **Save** button. The following status message appears at the top of the page:

Successfully inserted crossmatch record.

8. To enter results into another tray, repeat steps 4 through 7.

Accessing and Editing Crossmatch Results

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Click on the **X Match Results** button on the left menu. The Crossmatch Results Search screen will display.




Crossmatch Results Search

Search Criteria


Date Entered: Between And

Donor ID:

.....

3. To search for results that have already been entered or begun, enter the **Donor ID** number or **Date Entered** into the fields provided, and click on **Search**. A list will display with the search results.

Crossmatch Results 

ID	Donor ID	Tray Name	Tray Date	Tray Status	Donor Name	ABO
286	oj3004	NEOB-O	10/29/2001	unc	Test, Donor	A





Page 1 of 1

Search Criteria: [Legend]
Donor ID = OJ3004

Note: A search with no criteria entered will display crossmatches added within the last 3 days.

4. Click on the tray you wish to view or modify.

Crossmatch Results

For Donor ID: oj3004


Donor Name: Test, Donor ABO: A
 Tray Name: NEOB-O Tray Date: 07/30/2001
 Tray ID: 597 Lab: NEOB
 Crossmatch ID: 286 Crossmatch Entered On: 10/29/2001 11:41
 Crossmatch Entered By: MAOB

SSN	Center	ABO Name	Row	Result	Peak PRA	Current PRA	Serum (month/year)
111-22-3333	MAHM	B	Candidate, Liver	1A/1	1	50	50 01/2001

Note: Click the **LEGEND** button at the bottom of the screen to see a description of each result code.

5. To modify a tray, click on the **Edit** button. You may enter or change the **Result** fields.

Row	Result
1A/1	0 ▾
1B/2	0 ▾
1C/3	0 ▾
1D/4	0 ▾

6. Click the  button after entering your changes, and the following message will appear at the top of the page:

Successfully updated crossmatch record.

7. To delete a crossmatch result record, click the  button. The following message will appear:

Crossmatch Results

Successfully deleted crossmatch.



[No records were returned as a result of your search. Please select back to try again.]

Feedback

Accessing and Editing Donor Feedback

The disposition of organs from every donor is recorded through the Donor Feedback function in UNetSM. Feedback must be submitted within three working days of the transplant date.

To view a list of donors who have open (incomplete) feedback, take the following steps:

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Click on the **Feedback** button on the left menu. The Open Donor Feedback page is displayed:

Open Donor Feedback

Institution
22P001 - MAOB - New England Organ Bank
Feedback is incomplete for the following donors.

Donors created more than 30 days ago

Created	Donor ID	Donor Name	Referred From
---------	----------	------------	---------------




Donors created between 5 and 30 days ago

Created	Donor ID	Donor Name	Referred From
---------	----------	------------	---------------

Donors created less than 5 days ago

Created	Donor ID	Donor Name	Referred From
10/13/2001	OJN001	Robinson, Test	ATLANTICARE UNION HOSPITAL

3. Select a donor from the list and click on the **Donor ID**. The Report Donor Feedback page will display.

Report Donor Feedback				
  				
FEEDBACK OPEN				
Information for Donor ID: OJM001				
OPO:	22P001- MAOB- New England Organ Bank			
Donor Hospital:	220035 - ATLANTICARE UNION HOSPITAL			
Histocompatibility Lab:	<input type="text"/>			
Donor Name:	Robinson, Test			
Date of Referral Call:	<input type="text"/>			
Recovery Date:	<input type="text"/>			
Referral Only:	<input checked="" type="radio"/> YES <input type="radio"/> NO			
Disposition of Donor Organs				
Organ:	Disposition(supply code):	Code:	Match ID:	Tx Center:
Right Kidney	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Left Kidney	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

4. Enter all applicable information.
5. For Referrals, enter the **Date of Referral Call** and click on the **Referral Only Yes** button. A referral is when no consent was requested or obtained. After the feedback record has been updated, the Referral Only field will be read-only and can only be modified by UNOS.
6. The histocompatibility lab and recovery date are not required if the disposition for all organs is either Consent Not Requested, Consent Not Obtained or Organ Not Recovered is selected for all organs from the Disposition.

If Recovered Not for Tx, Recovered Not for Tx but Not Tx or Transplanted is selected for any organ disposition, then histocompatibility lab and recovery date are required.

7. For donors, a disposition must be entered for each organ type. For organs that were transplanted, a disposition **Code**, **Match ID** of the match that was used to allocate the organ, and the **TX Center** code of the recipient center are required. Click on the **Code** and **TX Center** column headings to display information tables.
8. Click the **Update** button at the top or bottom of the page to save this information. A message will display asking you if Feedback is complete. If you click **OK**, a message will appear at the top of the page that the record has successfully updated. Once completed this record no longer appears on the list of Open Donor Feedback.

Note: The Cadaver Donor Registration (CDR) form will be generated in Tiedi when feedback is complete. The Donor Histocompatibility (DH) form will generate as well, as long as at least one organ disposition is Recovered not for Tx, Recovered for Tx but not Tx, or Transplanted.

Payback

Viewing Payback Transactions

The Payback section of Placement displays a history of Payback transactions that have been recorded for your OPO.

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Click on the **Payback** button on the left menu. The Payback Accounting Search page is displayed.

Payback Accounting Search

Search using the criteria below:

Payback System:

UNDS A Kidney Payback (long-term) ▲
UNDS B Kidney Payback (long-term) ▾
UNDS AB Kidney Payback (long-term) ▾
UNDS O Kidney Payback (long-term) ▾

Transaction Type:
☒ Debts
☐ Credits

☒ Outstanding
☐ Cancelled

Transaction Date:
Between and

3. Choose a **Payback System** using the up or down arrows to view the list. You can select more than one system by holding down the Ctrl key while clicking with your mouse.
 4. Enter search criteria (either **Debts** or **Credits**), and check **Outstanding** or **Cancelled**.
 5. An optional **Transaction Date** range may be entered, using the MM/DD/YYYY format.
- Note:** The system will automatically fill in the current date as the ending date.
6. Click on **Search** to view the Payback Debt Accounting page.
 7. To view further information about a payback transaction, you may click on the **Date**.

Payback Debt Accounting for MAOB									
System	Date	Time	From	Donor ID	Share Type	Date	Sent To	Donor ID	Share Type
UNOS B (R)	11/02/2000	08:01:00	ILIP	NKA039	OMM				

PTR

Expected PTR Data

PTR (Potential Transplant Recipient) data is entered on every donor/recipient match that is used to allocate an organ. This information includes whether the organ was accepted, the date/time the potential recipient center was contacted, the name of the individual who accepted/rejected the organ offer and the primary reason that the organ offer was rejected by the center. UNetSM donor/recipient matches provide for this data to be entered directly into the match for every transplant candidate listed on the match. The match will remain with a PTR status of *open* or *expected* until the data is entered and the match is closed at the point that organ offers are stopped. If the PTR data is still open for more than 15 days, the data will be considered *overdue*.

The Expected PTR Data section allows you to view, enter and close matches with open PTR data.

To access a list of open or expected PTR data, take the following steps:

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Click on the **PTR** button on the left menu. The Expected PTR Data page will display by default.

Expected PTR Data	
Newland Organ Bank - NEOB	
0 - 15 Days (Current)	4
16 - 20 Days (Overdue)	0
21 - 25 Days (Overdue)	0
26 - 30 Days (Overdue)	0
Greater than 30 Days (Overdue)	40
Total Overdue	40
Total Expected	44

3. Expected PTR data is grouped by Current and Overdue categories. The **Total Overdue** category displays all PTR data that has been expected for over 15 days. The **Total Expected** category includes all of your center's Current and Overdue PTRs. Click on the category of your choice, and the applicable PTR Report will display.

Expected PTR Report									
PTR 0-15 Days (Current)									

4. Click on each listed Match ID to enter PTR data and/or to close the match.

5. The Feedback Match ID column displays a Match ID on which the donor's feedback was completed, if applicable.
6. The L/I column indicates if the donor is a local or import donor.
7. The Closed Seq # column displays the sequence number at which the match has been closed.
8. The Missing Seq # column displays the first sequence number on the match that is missing PTR information. When you click on the **Match ID**, you will be taken directly to this first missing sequence number.

Note: You may click on the [Legend] button at the bottom right corner of the screen to view the definitions for these columns.

9. Click the **Back** button to return to the Expected PTR Data screen and to enter PTR data on another expected match.

PTR Offer Import

PTR Offer data may be entered into a tab-delimited text file and imported directly into UNetSM. The file will be imported into the applicable match run, based upon the Match ID and the patient data contained in the file. To begin this process, complete the steps for exporting PTR Offers data as described in **Exporting PTR Data**. This file may be opened in a spreadsheet so that data can be entered for the candidates on the match, saved as a tab-delimited text file and then be imported back into UNet. The import process is a simulation of the manual PTR entry process in UNet. A file layout for the PTR Offers file is found in the News section under File Layouts.

1. After completing the steps for exporting PTR Offers, open the tab-delimited text file as shown in the example below. With no PTR data entered on the match, the file will export with only six fields populated: Match ID (#1), PTR Sequence Number (#2), Type (#4), SSN (#5), Center Code (#6) and Center Type (#7).

72348	1	C	111223333	ALUA	TX1
72348	2	C	111334444	ALUA	TX1
72348	3	C	222222222	MOOA	TX1
72348	4	C	333333333	MOOA	TX1
72348	5	C	222119999	MOOA	TX1
72348	6	C	999887777	MOAB	TX1
72348	7	C	999999999	MOOH	TX1
72348	8	C	888899999	AXUB	TX1
72348	9	C	222222277	BLUA	TX1
72348	10	C	777777777	BING	TX1

Note: If you are opening the text file into a spreadsheet, make sure the fields are formatted to be **TEXT** fields, not **NUMERIC** fields. A numeric field on a spreadsheet will drop any leading zeros in the SSN and may cause problems when importing the data.

The **C** in the Type field (#4) of this file indicates that the entered refusal or acceptance information is for the individual candidate. The **C** can be changed to a **T** to indicate a transplant center refusal, or an **R** to indicate a range refusal as shown in the example below.

72348	1		T	111223333	ALUA	TX1	N	10/18/2001	10:00	John	Doe	921
72348	2		C	111334444	ALUA	TX1						
72348	3	9	R	222222222	MOOA	TX1	N	10/18/2001	2:00	Sandy	Doe	991
72348	4		C	333333333	MOOA	TX1						
72348	5		C	222119999	MOOA	TX1						
72348	6		C	999887777	MOOA	TX1						
72348	7		C	999999999	MOAB	TX1						
72348	8		C	888899999	AXUB	TX1						
72348	9		C	222222277	BULA	TX1						
72348	10		C	777777777	BING	TX1	Y	10/18/2001	5:00	Mark	Doe	R

When entering a refusal, the following fields need to be entered: Offer Accept, Post Recovery Respond Date and Time, Contact First Name, Contact Last Name and Primary OPO Refusal Code. When entering a transplant center refusal, this information should only be entered for the transplant center's first potential recipient on the list. This patient's record and all subsequent patient records for the same transplant center will be updated with the same refusal information when the file is imported. In the example above, sequence numbers 1 and 2 will be updated with the same refusal information.

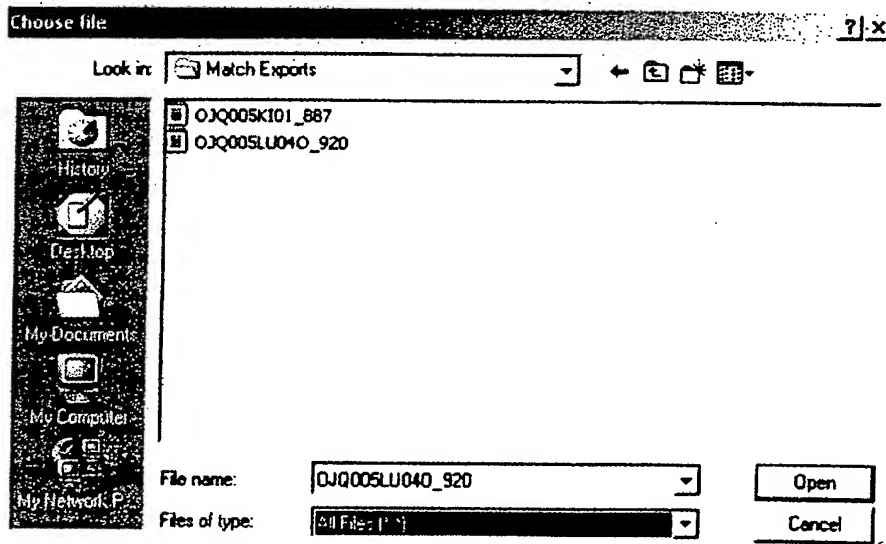
For range refusals, enter the Ending PTR Sequence Number in the third field of the file, along with the refusal information. The refusal code must be either 906, 991 - 996 or 998. The update will be applied to this potential recipient and potential recipients through this number when the file is imported. In the example above, a range refusal has been entered for sequence numbers 3 through 9.

Note: The PTR Refusal Other Specify field is not displayed in the file example above, but must be entered when a code 998 is entered into the Refusal Code field (#12).

To indicate an organ offer acceptance, enter a Y in the Offer Accept field (#8) of the applicable potential recipient. The Post Recovery Respond Date and Time, Contact First Name, Contact Last Name, Organ Placed are required. A Y may be entered in the 14th field, if the match should be closed at this sequence number.

- After all data has been entered, save the file as a tab-delimited text file.
- To import the file into UNetSM, click on the **PTR** button from the Placement menu. Click the **PTR Offer Import** button. The Upload PTR Offer Data File screen will display.

- You may enter the filename and its location or click **Browse** to select the file to be uploaded. The *Choose file* dialog box is displayed.



5. Locate and select the file to upload, and then click **Open**.

Enter Filename:	
M:\Importing and Exporting files\OJQ005LU04O_920.TXT	Browse...

6. Click on the **Save** button to upload the file.
7. If you are importing one match run, the UNet server will process your request immediately and information about the file will display as shown below. However, when importing multiple match runs, your request will be sent to the UNet server to be processed overnight. You will receive an email when the import request is complete, listing the number of records that processed or did not process, and the number of records with errors.

Information About The Uploaded File	
Upload filename	M:\Importing and Exporting files\OJQ005LU04O_920.TXT (5498 bytes)
Total Records in File	15
Total Records Processed	15
Total Records Not Processed	0
Total Records With Errors	0

Note: A range refusal or TXC refusal will be counted as only one record processed, rather than counting all the records that were updated with the TXC or range refusal information. Also, any existing PTR data entered on the match will not be overwritten by the import process.

8. You may also view the imported PTR information for accuracy by accessing the specific donor and match imported. Instructions on accessing a match are described in the Running a Match topic.

The following file layout is found in the News section, under the File Layouts option. We have also included the table for Organ Placed (field #13).

PTR Offer Export/Import Tab Delimited Text File Structure

Field #	Label	Type (Len)	Values/Notes
1	Match ID	N(10)	Required
2	PTR Sequence Number	N(10)	Required
3	Ending PTR Sequence Number	N(10)	Required for Range Refusal
4	Type	A(1)	C (Candidate), T (TXC Refusal), R (Range Refusal)
5	SSN	A(9)	Required
6	Center Code	A(4)	Required
7	Center Type	A(3)	Required
8	Offer Accept	A(1)	Y or N. If any other value row is not processed
9	Post Recovery Respond Date	A(19)	Required (format MM/DD/YYYY HH:MM)
10	Contact First Name	A(15)	First or Last Name required if Offer Accept is Y
11	Contact Last Name	A(25)	First or Last Name required if Offer Accept is Y
12	Refusal Code	N(3)	Required if Offer Accept is N
13	Organ Placed	A(2)	Required if Offer Accept is Y
14	Close Sequence Number	A(1)	Y to close match at PTR Sequence Number
15	PTR Refusal Other Specify	A(75)	Required if Primary OPO Refusal Code is 998

Organ Placed Table

Code	Organ	Description
B	KI	Both Kidneys
L	KI	Left Kidney
R	KI	Right Kidney
B	KP	Both Kidneys
BI	KP	Both Kidneys, Pancreas Islet
BW	KP	Both Kidneys, Whole Pancreas
L	KP	Left Kidney
LI	KP	Left Kidney, Pancreas Islet
LW	KP	Left Kidney, Whole Pancreas
R	KP	Right Kidney
RI	KP	Right Kidney, Pancreas Islet
RW	KP	Right Kidney, Whole Pancreas
I	KP	Pancreas Islet
W	KP	Whole Pancreas
I	PA	Pancreas Islet
W	PA	Whole Pancreas
S	LI	Liver Segment
W	LI	Whole Liver
S	IN	Intestine Segment
W	IN	Whole Intestine
HR	HR	Heart
HR	HL	Heart
HL	HL	Heart, Both Lungs
B	LU	Both Lung
BS	LU	Both Lung Segments
HL	LU	Heart, Both Lungs
L	LU	Left Lung
LS	LU	Left Lung Segment
LR	LU	Left Lung, Right Lung Segment
R	LU	Right Lung
RS	LU	Right Lung Segment
RL	LU	Right Lung, Left Lung Segment

Entering Donor Referral Data

In order to assess the impact of the Medicare and Medicaid Hospital Conditions of Participation for Organ, Tissue and Eye Donation on hospital organ donation practices, OPOs are required to provide donor hospital-specific data on donor referrals and organ recoveries. This reporting began in September 2001 for referrals made to your organization during the month of August 2001.

On the first day of each month, a new table will be provided for the OPO to record donor referrals for the preceding month. To enter the donor referral data, take the following steps:

1. Begin your Placement session. (See *Beginning a Session in Placement*)
2. Click on the **Referral Data** button on the left menu. The Donor Hospital Referral Data page is displayed for your center.

Donor Hospital Referral Data for NBOB - OP1

2001 (incomplete)

September (incomplete)

August (incomplete)

April (incomplete)

March (incomplete)

3. Each listed month will be noted as *complete* or *incomplete*. Months indicated as *incomplete* require data entry. Months indicated as *complete* do not require further data entry, although they will remain editable if any changes need to be made. Click on the applicable month to display the Donor Hospital Referral Data page for that month.

September 2001 - Donor Hospital Referral Data for NBOB - OP1

Provider # ▼, Hospital ▼	Referral	Eligible	Consent	Recovered/Transplanted	
Sorted by Provider#					
010144 SPRINGHILL MEMORIAL HOSP MOBILE, AL 36608	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HR: 0 / 0 KI: 0 / 0 LU: 0 / 0	IN: 0 / 0 LI: 0 / 0 PA: 0 / 0
010145 AMI WEST ALABAMA GENERAL HOSP NORTHPORT, AL 35476	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HR: 0 / 0 KI: 0 / 0 LU: 0 / 0	IN: 0 / 0 LI: 0 / 0 PA: 0 / 0
030002 GOOD SAMARITAN MED CTR PHOENIX, AZ 85006	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HR: 0 / 0 KI: 0 / 0 LU: 0 / 0	IN: 0 / 0 LI: 0 / 0 PA: 0 / 0
070001 THE HOSPITAL OF ST. RAPHAEL NEW HAVEN, CT 06511	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HR: 0 / 0 KI: 0 / 0 LU: 0 / 0	IN: 0 / 0 LI: 0 / 0 PA: 0 / 0

4. The list is grouped by donor hospital provider number, but can be re-sorted by hospital name by clicking on the red arrow. You must enter the number of **Referrals**, **Eligible** referrals and **Consents** obtained during the month. Tabbing to each field may help to speed up the data entry process. The number of organs Recovered and Transplanted will automatically display on the screen. The fields are defined as follows:

Referral: Any patient who is referred by a donor hospital for consideration of organ, tissue and/or eye donation.

Eligible: Any patient who is referred, evaluated and meets organ donor eligibility requirements. An eligible organ donor is defined as follows:

Any patient aged 70 or younger meeting death by neurological criteria, based on the American Academy of Neurology Practice parameters for determining brain death, who does not have any of the following indications:

Tuberculosis

Human Immunodeficiency Virus Infection with Specified Conditions

Creutzfeldt-Jacob Disease

Herpetic Septicemia

Rabies

Reactive Hepatitis B Surface Antigen

Any Retro virus infection

Active Malignant Neoplasms, except Primary CNS tumors and skin cancers

Hodgkin's Disease, Multiple Myeloma, Leukemia

Miscellaneous Carcinomas

Aplastic Anemia

Agranulocytosis

Fungal and Viral Meningitis

Viral Encephalitis

Gangrene of Bowel

Extreme Immaturity

Positive Serological or Viral Culture Findings for HIV

Consent: The number of consents that were obtained on referrals meeting organ donor eligibility requirements.

Recovered/Transplanted: The number of organs that were reported as recovered and transplanted from the specified donor hospital. This information is obtained from the donor record and completed Donor Feedback.


Note: These definitions can also be found by clicking on the Legend button located at the bottom right corner of the Donor Hospital Referral Data page.

5. After entering data in the fields for **Referral**, **Eligible** and **Consent**, click on the **Update** button to save this information.

Note: If there were no donor referrals from a listed donor hospital during the month, enter a zero in the **Referral** field. The **Eligible** and **Consent** fields for the donor hospital will then default to zero as you move to the next field.



If the donor hospital is not in your service area any longer, you may inactivate the donor hospital so it will not show up in future lists by following the instructions for **Inactivating a Donor Hospital**. Hospitals that are inactivated within a particular month will still display on that month's report. This allows any referrals to be reported for the time that the hospital was noted as Active in UNet.

Adding a Donor Hospital to the Donor Referral List

1. If you received a referral from a donor hospital that is not on your list, you may add the donor hospital to this month's report, by clicking on the  button. The Provider Search page will display.

Provider Search
Search to see if Provider number already exists :

Number:




2. Enter the 6-digit Medicare provider number for the donor hospital and click the **Search** button. If the provider number already exists in UNetSM, the hospital name will appear. Select the hospital and click the **Add** button. More than one hospital can be listed with the same provider number. Simply fill out the required fields and click the **Add** button. The new hospital will display on your list.

Add New September 2001 Referral Provider for MAOB-OP1
Provider Number: 440184

Current Providers Not on Referral List
440184 - NORTHSIDE HOSP JOHNSON CITY, TN 37601

Add only if Provider Not listed above

Provider #: R 440184
Name: R
City: R
State: R -
Zip: R -

If the provider does not currently appear on your list or is not in UNet's list of providers, a screen will display for you to add the new provider for this month's report. Enter all required information and click the **Add** button.

Add New September 2001 Referral Provider for MAOB-OP1
Provider Number: 123444

No records returned from search.

Provider #: R 123444
Name: R
City: R
State: R
Zip: R

When searching for a provider number, you will be prompted if the provider is already included in your list of donor hospitals. If necessary, you may add another hospital with the same provider number by following the steps above.

3. The newly added donor hospital will appear in the current month's list and a request will be sent to have the hospital added to the UNetSM system's list of provider numbers. If you wish the donor hospital to appear on future reports, you will need to add the donor hospital to your list of hospitals by following the instructions under ***Adding/Deleting a Donor Hospital***.

Placement Form Field Descriptions

Donor Forms

Local Cadaver Donor Search Form

One or more criteria may be entered when searching for a local donor.

Add Date: Enter inclusive dates for the donor's add date in the boxes labeled "Between" & "and".

Donor ID: Enter the donor ID number in the selection box.

Donor Hospital: Select the correct donor hospital.

Last Name: Enter the donor's last name.

Age Range: Enter the donor age range in the "Between" & "and". Then select an age unit of years or months.

ABO: Select a blood type.

Local Cadaver Donor Form

The fields on the Local Cadaver Donor form contain demographic and basic clinical information about the donors.

Note: *You may edit incorrect data on the form if you have access to do so. Otherwise, you will only be able to view the form. If you have questions about your security access, contact your system administrator.*

UNOS ID

OPO: Verify that the OPO provider number printed on the form is the 6-character Medicare identification number of the OPO responsible for the management of this donor. A list of valid OPO provider numbers is available in the Information Tables section. Also preprinted are the four digit OPO code and the name of the OPO.

Donor Hospital: Select the name of the hospital that originally referred the donor. This is a required field.

Last Name: Enter the last name of the donor who was referred to your OPO as a potential organ donor. This is a required field.

First Name: Enter the first name of the donor who was referred to your OPO as a potential organ donor. This is a required field.

Ethnicity: Select the donor's ethnicity from the selection box. This is a required field.

Hispanic/Latino: Select only if the candidate is of Mexican, Puerto Rican, Cuban, Central and South American and other Spanish cultures or origin.

Non-Hispanic/Non-Latino: Select only if the candidate is not of a culture or origin described above, regardless of race.

Race: Select all that apply to indicate the donor's race. This is a required field.

White: Select for candidates having origins in any of the original peoples of Europe.

Black or African American: Select for candidates having origins in any of the black racial groups of Africa.

American Indian/Alaska Native: Select for candidates having origins in any of the original peoples of North and South America, and who maintain cultural identification through tribal affiliation or community attachment.

Asian: Select for candidates having origins in any of the original peoples of the Far East and Southeast Asia. Examples of this area include China, Japan, Korea, and Philippine Islands.

Native Hawaiian or other Pacific Islander: Select for candidates having origins in any of the peoples of the Hawaii, Guam, Samoa, or other Pacific Islands.

Mid-East or Arabian: Select for candidates having origins in any of the peoples of the Middle East and Northern Africa. Examples of this area include Egypt, Israel, Iran, Iraq, Saudi Arabia, Jordan, and Kuwait.

Indian Sub-Continent: Select for candidates having origins in any of the peoples of the Indian Sub-Continent. Examples of this area include India and Pakistan.

MATCH RUN INFORMATION

Gender: Select the appropriate field for **Male** or **Female**.

Age: Enter the donor's age. The age must fall between 0 and 99. Then indicate the **Years** or **Months**.

DOB: Enter the date of the donor's birth, using the MM/DD/YYYY format.

ABO: Enter the appropriate blood group for the donor: O, A, B, AB, A1, A2, A1B, or A2B.

Height: Enter the height of the donor in the appropriate space, in feet and inches or centimeters. The height must fall between 0 and 7 feet or 1 and 225 centimeters.

Weight: Enter the weight of the donor in the appropriate space, in pounds or kilograms. The weight must fall between 0 and 440 pounds or 0 and 200 kilograms.

MATCH RUNS REQUESTED

Check off all matches to be run. To save the record and run these matches. Click the Run Match button.

Kidney
Kidney/Pancreas
Pancreas
Heart
Heart/Lung
Lung
Liver
Intestine

ADDITIONAL MATCH RUN INFORMATION

HCV Antibody: Indicate whether the HCV antibody is Positive, Negative or Not Done.

Hepatitis B Core Antibody: Indicate whether the Hepatitis B core antibody is Positive, Negative or Not Done from the selection box.

HLA (Human Leukocyte Antigen): Indicate the donor's HLA. This must be entered when running kidney, kidney/pancreas and pancreas matches.

Previous Gastrointestinal Disease: Yes if donor had previous gastrointestinal disease. If not, select No. If unknown, select UNK. This must be Yes or No when running an intestine match.

Is there time for a Preliminary Crossmatch? Yes defaulted but may be changed if there is not time for a preliminary crossmatch.

Select crossmatch results: Select any crossmatch trays to be included for screening positive crossmatches off of the list. A No crossmatches stored message will appear if there are no crossmatch results available.

OPTIONAL MATCH RUN INFORMATION

This information is used to further screen potential recipients off the match run who cannot accept a donor kidney after a certain amount of ischemic time, glomerular sclerosis or serum creatinine.

Warm Ischemic time: Enter the time in minutes.

Cold Ischemic time upon arrival: Enter the time in hours.

Placement

Placement Form Field Descriptions

Glomeruli Observed on Kidney biopsy: Enter Yes or No.

Percent Glomerular Sclerosis on Kidney biopsy: Enter the percent amount.

Peak serum creatinine: Enter the amount in mg/dl.

Final serum creatinine: Enter the amount in mg/dl.

Import Donor Form

The fields on the Import Donor form contain demographic and basic clinical information about the import cadaver donor.

Note: *If you are unable to access the import donor record, contact the originating OPO to verify that Import Access has been given. (See Giving Import Access to Another OPO for more information.)*

UNOS ID

OPO: Verify that the OPO provider number printed on the form is the 6-character Medicare identification number of the OPO responsible for the management of this donor. A list of valid OPO provider numbers is available in the Information Tables section. Also preprinted are the four digit OPO code and the name of the OPO.

Donor Hospital: Select the name of the hospital that referred the donor. This is a required field.

Last Name: Enter the last name of the donor. This is a required field.

First Name: Enter the first name of the donor. This is a required field.

Ethnicity: Select the donor's ethnicity from the selection box. This is a required field.

Hispanic/Latino: Select only if the candidate is of Mexican, Puerto Rican, Cuban, Central and South American and other Spanish cultures or origin.

Non-Hispanic/Non-Latino: Select only if the candidate is not of a culture or origin described above, regardless of race.

Race: Select all that apply to indicate the donor's race. This is a required field.

White: Select for candidates having origins in any of the original peoples of Europe.

Black or African American: Select for candidates having origins in any of the black racial groups of Africa.

American Indian/Alaska Native: Select for candidates having origins in any of the original peoples of North and South America, and who maintain cultural identification through tribal affiliation or community attachment.

Asian: Select for candidates having origins in any of the original peoples of the Far East and Southeast Asia. Examples of this area include China, Japan, Korea, and Philippine Islands.

Native Hawaiian or other Pacific Islander: Select for candidates having origins in any of the peoples of the Hawaii, Guam, Samoa, or other Pacific Islands.

Mid-East or Arabian: Select for candidates having origins in any of the peoples of the Middle East and Northern Africa. Examples of this area include Egypt, Israel, Iran, Iraq, Saudi Arabia, Jordan, and Kuwait.

Indian Sub-Continent: Select for candidates having origins in any of the peoples of the Indian Sub-Continent. Examples of this area include India and Pakistan.

MATCH RUN INFORMATION

Gender: Select the appropriate field for **Male** or **Female**.

Age: Enter the donor's age. The age must fall between 0 and 99. Then indicate the **Years** or **Months**.

DOB: Enter the date of the donor's birth, using the MM/DD/YYYY format.

ABO: Enter the appropriate blood group for the donor: O, A, B, AB, A1, A2, A1B, or A2B.

Height: Enter the height of the donor in the appropriate space, in feet and inches or centimeters. The height must fall between 0 and 7 feet or 1 and 225 centimeters.

Weight: Enter the weight of the donor in the appropriate space, in pounds or kilograms. The weight must fall between 0 and 440 pounds or 0 and 200 kilograms.

MATCH RUNS REQUESTED

Check off all matches to be run. To save the record and run these matches. Click the Run Match button.

Kidney
Kidney/Pancreas
Pancreas
Heart
Heart/Lung
Lung
Liver
Intestine

ADDITIONAL MATCH RUN INFORMATION

HCV Antibody: Indicate whether the HCV antibody is Positive, Negative or Not Done.

Hepatitis B Core Antibody: Indicate whether the Hepatitis B core antibody is Positive, Negative or Not Done from the selection box.

HLA (Human Leukocyte Antigen): Indicate the donor's HLA. This must be entered when running kidney, kidney/pancreas and pancreas matches.

Previous Gastrointestinal Disease: Yes if donor had previous gastrointestinal disease. If not, select No. If unknown, select UNK. This must be Yes or No when running an intestine match.

Is there time for a Preliminary Crossmatch? Yes defaulted but may be changed if there is not time for a preliminary crossmatch.

Select crossmatch results: Select any crossmatch trays to be included for screening positive crossmatches off of the list. A No crossmatches stored message will appear if there are no crossmatch results available.

OPTIONAL MATCH RUN INFORMATION

This information is used to further screen potential recipients off the match run who cannot accept a donor kidney after a certain amount of ischemic time, glomerular sclerosis or serum creatinine.

Warm Ischemic time: Enter the time in minutes.

Cold Ischemic time upon arrival: Enter the time in hours.

Glomeruli Observed on Kidney biopsy: Enter Yes or No.

Percent Glomerular Sclerosis on Kidney biopsy: Enter the percent amount.

Peak serum creatinine: Enter the amount in mg/dl.

Final serum creatinine: Enter the amount in mg/dl.

Living Donor

The fields on the Living Donor form contain demographic and basic clinical information about the living donor.

Note: *In order to access Living Donor information, the work up transplant center must designate on the donor record that your OPO can run a match on that donor.*

UNOS ID

OPO: Verify that the OPO provider number printed on the form is the 6-character Medicare identification number of the OPO responsible for the management of this donor. A list of valid OPO provider numbers is available in the Information Tables section. Also preprinted are the four-digit OPO code and the name of the OPO.

Donor Hospital: Select the name of the hospital that originally referred the donor. This is a required field.

Last Name: Enter the last name of the donor who was referred to your OPO as a potential organ donor. This is a required field.

First Name: Enter the first name of the donor who was referred to your OPO as a potential organ donor. This is a required field.

Ethnicity: Select the donor's ethnicity from the selection box. This is a required field.

Hispanic/Latino: Select only if the candidate is of Mexican, Puerto Rican, Cuban, Central and South American and other Spanish cultures or origin.

Non-Hispanic/Non-Latino: Select only if the candidate is not of a culture or origin described above, regardless of race.

Race: Select all that apply to indicate the donor's race. This is a required field.

White: Select for candidates having origins in any of the original peoples of Europe.

Black or African American: Select for candidates having origins in any of the black racial groups of Africa.

American Indian/Alaska Native: Select for candidates having origins in any of the original peoples of North and South America, and who maintain cultural identification through tribal affiliation or community attachment.

Asian: Select for candidates having origins in any of the original peoples of the Far East and Southeast Asia. Examples of this area include China, Japan, Korea, and Philippine Islands.

Native Hawaiian or other Pacific Islander: Select for candidates having origins in any of the peoples of the Hawaii, Guam, Samoa, or other Pacific Islands.

Mid-East or Arabian: Select for candidates having origins in any of the peoples of the Middle East and Northern Africa. Examples of this area include Egypt, Israel, Iran, Iraq, Saudi Arabia, Jordan, and Kuwait.

Indian Sub-Continent: Select for candidates having origins in any of the peoples of the Indian Sub-Continent. Examples of this area include India and Pakistan.

MATCH RUN INFORMATION

Gender: Select the appropriate field for **Male** or **Female**.

Age: Enter the donor's age. The age must fall between 0 and 99. Then indicate **Years** or **Months**.

DOB: Enter the date of the donor's birth, using the MM/DD/YYYY format.

ABO: Enter the appropriate blood group for the donor: O, A, B, AB, A1, A2, A1B, or A2B.

Height: Enter the height of the donor in the appropriate space, in feet and inches or centimeters. The height must fall between 0 and 7 feet or 1 and 225 centimeters.

Weight: Enter the weight of the donor in the appropriate space, in pounds or kilograms. The weight must fall between 0 and 440 pounds or 0 and 200 kilograms.

MATCH RUNS REQUESTED

Check off all matches to be run. To save the record and run these matches. Click the Run Match button.

Kidney
Kidney/Pancreas
Pancreas
Heart
Heart/Lung
Lung
Liver
Intestine

ADDITIONAL MATCH RUN INFORMATION

HCV Antibody: Indicate whether the HCV antibody is Positive, Negative or Not Done.

Hepatitis B Core Antibody: Indicate whether the Hepatitis B core antibody is Positive, Negative or Not Done from the selection box.

HLA (Human Leukocyte Antigen): Indicate the donor's HLA. This must be entered when running kidney, kidney/pancreas and pancreas matches.

Previous Gastrointestinal Disease: Yes if donor had previous gastrointestinal disease. If not, select No. If unknown, select UNK. This must be Yes or No when running an intestine match.

Is there time for a Preliminary Crossmatch? Yes defaulted but may be changed if there is not time for a preliminary crossmatch.

Select crossmatch results: Select any crossmatch trays to be included for screening positive crossmatches off of the list. A No crossmatches stored message will appear if there are no crossmatch results available.

OPTIONAL MATCH RUN INFORMATION

This information is used to further screen potential recipients off the match run who cannot accept a donor kidney after a certain amount of ischemic time, glomerularsclerosis or serum creatinine.

Warm Ischemic time: Enter the time in minutes.

Cold Ischemic time upon arrival: Enter the time in hours.

Glomeruli Observed on Kidney biopsy: Enter Yes or No.

Placement

Placement Form Field Descriptions

Percent Glomerular Sclerosis on Kidney biopsy: Enter the percent amount.

Peak serum creatinine: Enter the amount in mg/dl.

Final serum creatinine: Enter the amount in mg/dl.

Test Donor

The fields on the Test Donor form contain demographic and basic clinical information about the test donors.

UNOS ID

OPO: Verify that the OPO provider number printed on the form is the 6-character Medicare identification number of the OPO responsible for the management of this donor. A list of valid OPO provider numbers is available in the Information Tables section. Also preprinted are the four-digit OPO code and the name of the OPO.

Donor Hospital: Select the name of the hospital that originally referred the donor. This is a required field.

Last Name: Enter the last name of the donor who was referred to your OPO as a potential organ donor. This is a required field.

First Name: Enter the first name of the donor who was referred to your OPO as a potential organ donor. This is a required field.

Ethnicity: Select the donor's ethnicity from the selection box. This is a required field.

Hispanic/Latino: Select only if the candidate is of Mexican, Puerto Rican, Cuban, Central and South American and other Spanish cultures or origin.

Non-Hispanic/Non-Latino: Select only if the candidate is not of a culture or origin described above, regardless of race.

Race: Select all that apply to indicate the donor's race. This is a required field.

White: Select for candidates having origins in any of the original peoples of Europe.

Black or African American: Select for candidates having origins in any of the black racial groups of Africa.

American Indian/Alaska Native: Select for candidates having origins in any of the original peoples of North and South America, and who maintain cultural identification through tribal affiliation or community attachment.

Asian: Select for candidates having origins in any of the original peoples of the Far East and Southeast Asia. Examples of this area include China, Japan, Korea, and Philippine Islands.

Native Hawaiian or other Pacific Islander: Select for candidates having origins in any of the peoples of the Hawaii, Guam, Samoa, or other Pacific Islands.

Mid-East or Arabian: Select for candidates having origins in any of the peoples of the Middle East and Northern Africa. Examples of this area include Egypt, Israel, Iran, Iraq, Saudi Arabia, Jordan, and Kuwait.

Indian Sub-Continent: Select for candidates having origins in any of the peoples of the Indian Sub-Continent. Examples of this area include India and Pakistan.

MATCH-RUN INFORMATION

Gender: Select the appropriate field for Male or Female.

Age: Enter the donor's age. The age must fall between 0 and 99. Then indicate Years or Months.

DOB: Enter the date of the donor's birth, using the MM/DD/YYYY format.

ABO: Enter the appropriate blood group for the donor: O, A, B, AB, A1, A2, A1B, or A2B.

Height: Enter the height of the donor in the appropriate space, in feet and inches or centimeters. The height must fall between 0 and 7 feet or 1 and 225 centimeters.

Weight: Enter the weight of the donor in the appropriate space, in pounds or kilograms. The weight must fall between 0 and 440 pounds or 0 and 200 kilograms.

MATCH RUNS REQUESTED

Check off all matches to be run. To save the record and run these matches. Click the Run Match button.

Kidney
Kidney/Pancreas
Pancreas
Heart
Heart/Lung
Lung
Liver
Intestine

ADDITIONAL MATCH RUN INFORMATION

HCV Antibody: Indicate whether the HCV antibody is Positive, Negative or Not Done.

Hepatitis B Core Antibody: Indicate whether the Hepatitis B core antibody is Positive, Negative or Not Done from the selection box.

HLA (Human Leukocyte Antigen): Indicate the donor's HLA. This must be entered when running kidney, kidney/pancreas and pancreas matches.

Previous Gastrointestinal Disease: Yes if donor had previous gastrointestinal disease. If not, select No. If unknown, select UNK. This must be Yes or No when running an intestine match.

Is there time for a Preliminary Crossmatch? Yes defaulted but may be changed if there is not time for a preliminary crossmatch.

Select crossmatch results: Select any crossmatch trays to be included for screening positive crossmatches off of the list. A No crossmatches stored message will appear if there are no crossmatch results available.

OPTIONAL MATCH RUN INFORMATION

This information is used to further screen potential recipients off the match run who cannot accept a donor kidney after a certain amount of ischemic time, glomerular sclerosis or serum creatinine.

Warm Ischemic time: Enter the time in minutes.

Cold Ischemic time upon arrival: Enter the time in hours.

Glomeruli Observed on Kidney biopsy: Enter Yes or No.

Percent Glomerular Sclerosis on Kidney biopsy: Enter the percent amount.

Peak serum creatinine: Enter the amount in mg/dl.

Final serum creatinine: Enter the amount in mg/dl.

Feedback Forms

Report Donor Feedback

The fields on the Report Donor Feedback form contain demographic and basic clinical information about referrals and recovered organs.

Note: To correct data on completed Report Donor Feedback forms, you may contact the Help Desk by calling 1-800-978-4334 or emailing unoshelpdesk@unos.org.

FEEDBACK OPEN

Information for Donor ID: The Donor ID number is preprinted.

OPO: The OPO name is preprinted.

Donor Hospital: The hospital name is preprinted.

Histocompatibility Lab: Select the appropriate institution from the list.

Donor Name: The donor's name is preprinted.

Date of Referral Call: Enter the referral call date in MM/DD/YYYY format.

Recovery Date: Enter the recovery date in MM/DD/YYYY format.

Referral Only: Indicate whether or not this is only a referral by selecting **Yes** or **No** in the appropriate circle.

DISPOSITION OF DONOR ORGANS

Organ:

Right Kidney
Left Kidney
Double/En-bloc Kidney
Pancreas
Pancreas Segment 1
Pancreas Segment 2
Liver
Liver Segment 1
Liver Segment 2
Intestine
Intestine Segment 1

Disposition (Supply Code): For each organ that applies, indicate whether the disposition supply code is: Consent Not Requested, Consent Not Obtained, Organ Not Recovered, Recovered Not for Tx, Recovered for TX but not Tx or Transplanted.

Note: When selecting a disposition supply code for each organ, you will not be able to select a whole organ and each of its separate organs simultaneously. For example, when selecting codes for a right kidney and left kidney, you will not be able to make a selection for a double/en-bloc kidney.

Code: Enter the disposition reason code for each organ by clicking the **Code** link at the top of the column. (See *Disposition Reason Codes*.)

Match ID: Indicate the appropriate Match ID number from the selection box for each organ.

Tx Center: Select the correct transplant centers for all transplanted organs.

Information Tables

Disposition Reason Codes

REASON CONSENT NOT REQUESTED	
10	Donor Age
11	Non-heart beating donor (Valid only for HR, LU, IN, PA)
12	History of Previous Cardiac Surgery (Valid only for HR)
13	History of Severe Cardiac Disease (Valid only for HR)
14	History of Lung Disease (Valid only for LU)
15	History of Gastro-Intestinal Disease (Valid only for IN)
16	History of Diabetes Mellitus (Valid only for PA)
17	Pancreatitis (Valid only for PA)
18	Acute/Chronic Renal Failure
21	Donor Quality
22	Donor ABO
99	Other Specify
REASON CONSENT NOT OBTAINED	
100	Emotional
101	Cultural Beliefs
102	Religious Beliefs
103	Family Conflict
199	Other Specify
REASON ORGAN NOT RECOVERED	
200	Poor Organ Function
201	Cardiac Arrest
202	Infection
203	Positive Hepatitis
204	Positive HIV
205	Diseased Organ
206	Anatomical Abnormalities
207	Vascular Damage
208	No Recipient Located
209	Donor Medical History
210	Donor Social History
211	Positive HTLV-1
212	Biopsy Findings
213	Surgical Damage in OR
214	No Local Recover Team
215	Organ Refused By All Regional Program
216	Organ Refused by All National Program
217	Organ Refused by all Programs with Urgent Need
218	Ruled Out after Evaluation in OR
219	Ruled Out Due to Biopsy
220	Ejection Fraction < 50%

221	Po2 < 200 ON o2 Challenge
222	Hemodynamically Unstable Donor
223	Trauma to Organ
224	+ Gram Stain
225	Time Constraints
226	Medical Examiner Restricted
299	Other Specify
RECOVERED NOT FOR TRANSPLANT	
510	Recovered for Research
511	Recovered for Heart Valves
512	Recovered for Pancreas Islet Cells
513	Recovered for Extra-corporeal Liver
515	Recovered only for Purpose Hepocytes
RECOVERED FOR TRANSPLANT BUT NOT TRANSPLANTED	
503	Recovered for Transplant: Discarded Locally
504	Recovered for Transplant: Shared and Discarded
505	Recovered for Transplant: Submitted for Research
506	Recovered for Transplant: Sent for Heart Valves
507	Organ Exported Outside of U.S.
508	Recovered for Transplant: Sent for Pancreas Islets
509	Recovered for Transplant: Sent for Ex-corp Liver
514	Recovered for Transplant: Sent for Hepatocytes
TRANSPLANTED	
501	Organ Transplanted Locally
502	Organ Transplanted Shared

Disposition Supply Codes

FROM THE REPORT DONOR FEEDBACK FORM
Consent Not Requested
Consent Not Obtained
Organ Not Recovered
Recovered for TX but not Tx
Transplanted

Potential Recipient Refusal Codes

Code	Refusal Reason	Description
RECIPIENT RELATED REASONS		
901	Recipient ill	recipient too sick to attempt transplant at the time of offer
902	Recipient Unavailable	recipient cannot be contacted, not ready for transplant or has died at the time of offer
903	Recipient refused	recipient refused transplant at the time of offer
904	Multiple organ transplant required	recipient requires multiple organ transplant, other required organ(s) not available from the specified donor at the time of offer
905	Recipient transplanted/inactive	recipient already transplanted or is on the inactive list at the time of offer
906	Positive crossmatch	crossmatch results between donor and recipient positive
907	HLA mismatch unacceptable	HLA mismatch between donor and recipient unacceptable
908	Recipient testing results unavailable, not done or unacceptable	recipient requires a crossmatch at time of offer, high PRA, no current tissue typing or any other recipient testing
909	Patient's condition improved, transplant not needed	recipients condition has improved and transplant is currently unnecessary
910	Recipient Medical Urgency	recipient bypassed due to medical urgency of another recipient (requires written verification by transplant surgeon)
PROGRAM RELATED REASONS		
911	Heavy workload	program unable to accept an organ at this time due to heavy workload
912	Operational	transportation, logistics, distance, exceeded one hour response time or placement time constraints related to organ ischemic time
913	Surgeon Unavailable	surgeon currently performing
GENERAL DONOR ISSUES		
921	Donor quality	hypertension, prolonged hypotension, high vasopressor/ medication dosage, cardiac arrest, evidence of infection/positive cultures, non-heart beating, etiology of death, donor unstable, donor diabetes, other medical history
922	Donor age	donor too old or young
923	Donor size/weight	donor too large or small, weight incompatible with recipient
924	Donor ABO	donor ABO group incompatible/unacceptable
925	Donor social history	history of high risk sexual behavior, alcohol or IV drug use
926	Positive serological tests	CMV, HBV, HCV, HIV, HTLV, VDRL, etc. donor testing is positive

927	Organ Preservation	method/quality of preservation, length of cold ischemic time, length of warm ischemic time, possible organ contamination, inadequate typing material, labeling/packaging problems
928	Organ anatomical damage or defect	surgical damage, non-surgical trauma, diseased organ, organ vasculature, enbloc kidney's or any other anatomical reason
ORGAN SPECIFIC DONOR ISSUES: KIDNEY		
930	Renal function test results unavailable, not done or unacceptable	Test results relating to renal function are not available or tests relating to renal function were not performed
931	Elevated creatinine	donor serum creatinine > 2.0 mg/dl
932	Abnormal urinalysis	presence of protein, WBCs, blood, etc. in donor urine
933	Abnormal biopsy	biopsy results indicate donor kidney unsuitable for transplant
934	Decreased urine output	urine output < 80 ml/ hour
ORGAN SPECIFIC DONOR ISSUES: LIVER		
940	Liver function test results unavailable, not done or unacceptable	test results relating to liver function are not available or tests relating to liver function were not performed
941	Rising serum transaminase	SGOT/AST or SGPT/ALT greater than 2x normal
942	Abnormal biopsy	biopsy results indicate donor liver unsuitable for transplant
ORGAN SPECIFIC DONOR ISSUES: HEART		
950	Cardiac function test results unavailable, not done or unacceptable	test results relating to cardiac function are not available or tests relating to cardiac function were not performed
951	Abnormal echocardiogram	echo showing wall motion abnormalities or valvular lesions
952	Abnormal coronary angiography	presence of coronary artery disease
953	Abnormal EKG results	Q-waves, ST-T abnormalities or conduction disease
954	Abnormal hemodynamics	elevated filling pressures or reduced cardiac output
ORGAN SPECIFIC DONOR ISSUES: PULMONARY		
960	Pulmonary function test results unavailable, not done or unacceptable	tests results relating to pulmonary function are not available or tests relating to pulmonary function were not performed
961	Abnormal arterial blood gases	arterial blood gas; pH or pCO ₂ or PO ₂ are outside acceptable ranges
962	Abnormal chest x-ray	evidence of infiltrate, trauma, pneumothorax or mass
963	Abnormal bronchoscopy results	evidence of infection, trauma or mass
OTHER		
991	Donor Medical Urgency	potential recipient was by-passed due to donor medical urgency or OPO time constraints.
992	Multi-organ placement	potential recipient was by-passed for priority

		multi-organ transplant
993	Directed donation	potential recipient was by-passed because the donation was directed to a specific recipient.
994	Military donor	potential recipient was by-passed because the organ was from a military donor and was directed to a military recipient.
995	ALU, Sharing Agreement, Variance	potential recipient was by-passed due to the OPO's alternative local unit, sharing agreement or variance.
996	Extra-renal placed with kidney	potential recipient was by-passed in order to place the extra-renal organ with the kidney recipient from the same donor.
998	Other Specify	Use only if the refusal reason does not fit the above categories. Be sure to write in the other reason, UNOS staff will review the OTHER reason and may recode if necessary.

HLA Antigen Tables

HLA A, B, and DR Matching Antigen Equivalences					
A LOCUS	EQUIVALENT	B LOCUS	EQUIVALENT	DR LOCUS	EQUIVALENT
1	1	5	<u>5,52,53,78</u>	1	1,103
2	2,203,210	7	<u>7,703</u>	2	2,15,16
3	3	8	8	3	3,17,18
9	9	12	12	4	4
10	<u>10,26,34,66,6601/2</u>	13	13	5	5,11,12
11	11	14	14,64,65	6	6,13,14,1403/4
19	19,74	15	<u>15,75,76,77,1304</u>	7	7
23	23	16	<u>16,3905</u>	8	8
24	24,2403	17	17,58	9	9
25	25	18	18	10	10
26	<u>26,6601</u>	21	<u>21,4005,1304</u>	11	11,5
28	28,68,69	22	<u>22,54,8201</u>	12	12,5
29	29	27	27	13	13,6
30	30	35	35	14	14,6,1403/4
31	31	37	37	15	15,2
32	32	38	38	16	16,2,15
33	33	39	<u>39,3901/2/5</u>	17	17,3,18
34	<u>34,6602</u>	40	<u>40,61,81,0804</u>	18	18,3,17
36	36	41	41	103	103,1
43	43	42	42	*1403	1403,14,6
66	<u>66,6601,6602,10</u>	44	44	*1404	1404,14,6
68	68,28	45	45	** 99	<u>(No equivalent)</u>
69	69,28	46	46		
74	74,19	47	47		
80	80	48	48		
203	203,2	49	49		
210	210,2	50	50,4005		
2403	2403,24	51	<u>51,5102,5103</u>		
*6601	<u>6601,66,10,26</u>	52	52,5		
*6602	<u>6602,66,10,34</u>	53	<u>53,5,5102</u>		
** 99	<u>(No equivalent)</u>	54	54,22		
		55	55		
		56	56		
		57	57		
		58	58		
		59	59		
		60	60		
		61	61,40		
		62	62		
		63	63		
		64	64,14		
		65	65,14		
		67	67		
		70	<u>70,71,72</u>		
		71	71,70		
		72	72,70		
		73	73		
		75	75,15		
		76	76,15		
		77	77,15		

	78	78,5	
	81	81,7,40,60,61,48	
	703	703,7	
	*0804	0804,8	
	*1304	1304,15,21,49,50	
	*1522	1522,35,70	
	*2708	2708,27,7	
	*3901	3901,39	
	*3902	3902,39	
	*3905	3905,16,39	
	*4005	4005,21,50	
	*5102	5102,51,53	
	*5103	5103,51	
	*8201	8201,45,22,54/5/6	
	** 99	(No equivalent)	

* Indicates an allele; may not have a WHO-approved serologic specificity

** Code 99 means not tested

HLA A, B, and DR Unacceptable Antigen Equivalences					
A LOCUS	EQUIVALENT	B LOCUS	EQUIVALENT	DR LOCUS	EQUIVALENT
1	1	5	5,51,5102/3,52,78	1	1,103
2	2,203,210	7	7,703	2	2,15,16
3	3	8	8,0804	3	3,17,18
9	9,23,24,2403	12	12,44,45	4	4
10	10,25,26,34,66,6601,6602	13	13	5	5,11,12
11	11	14	14,64,65	6	6,13,14,1403/4
19	19,29,30,31,32,33,74	15	15,62,63,75,76,77,1522	7	7
23	23	16	16,38,39	8	8
24	24,2403	17	17,57,58	9	9
25	25	18	18	10	10
26	26	21	21,49,50,4005	11	11
28	28,68,69	22	22,54,55,56	12	12
29	29	27	27,2708	13	13
30	30	35	35	14	14,1403/4
31	31	37	37	15	15
32	32	38	38	16	16
33	33	39	39,3901,3902,3905	17	17
34	34	40	40,60,61	18	18
36	36	41	41	51	(same as DR2)
43	43	42	42	52	3,5,6,11,12,13, 14,17,18,1403/4
66	66,6601,6602	44	44		
68	68	45	45	53	4,9
69	69	46	46	103	103
74	74	47	47	*1403	1403
80	80	48	48	*1404	1404
203	203	49	49		
210	212	50	50,4005		
*2403	2403	51	51,5102,5103		
*6601	6601	52	52		
*6602	6602	53	53		
		54	54		
		55	55		
		56	56		
		57	57		
		58	58		

	59	59	
	60	60	
	61	61	
	62	62	
	63	63	
	64	64	
	65	65	
	67	67	
	70	70,71,72	
	71	71	
	72	72	
	73	73	
	75	75	
	76	76	
	77	77	
	78	78	
	81	81	
	703	703	
	*0804	0804	
	*1304	1304	
	*1522	1522	
	*2708	2708	
	*3901	3901	
	*3902	3902	
	*3905	3905	
	*4005	4005	
	*5102	5102	
	*5103	5103	
	*8201	8201	
	BW4	***	
	BW6	***	

* Indicates an allele; may not have a WHO-approved serologic specificity

*** Please refer to the end of this section for information

Equivalents for BW4 and BW6:

BW4	5,13,17,27,37,38,44,47,49,51,52,53,57,58,59,63,77,1304,5102,5103
BW6	7,8,14,18,22,35,39,40,41,42,45,48,50,54,55,56,60,61,62,64,65,67,70,71,72,73,75,76,78,81,703,0804,1522,2708,3901,3902,3905,4005,8201

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U:NetSM

User's Manual

Tiedi[®]

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Data sources and structure

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Introduction

This article discusses a rich resource of data used to describe all aspects of transplantation, from donor and recipient characteristics to immunosuppression medications. These data are used by the SRTR, the OPTN, and a wide variety of other researchers as the basis for reporting on the state of transplantation in the United States, as well as answering a wide array of research questions. They are the source for the figures and tables in the OPTN/SRTR *Annual Report*. They form the basis for reporting on both OPTN and SRTR web sites, providing medical professionals and patients alike with the answers to such critical questions as: *How fast are waiting lists growing? Which center has experience serving patients like me? How quickly might I get an organ if I register at a different center, and are my prospects for survival after transplant there as good?* Finally, these data form the basis for extensive analyses in support of policy-setting by the Secretary's Advisory Committee on Transplantation (ACOT), OPTN/UNOS committees, and other government and nongovernment requesters: *Is a transplant candidate*

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better off accepting an organ from a less-than-ideal candidate or staying on a waiting list? How do antigen matching rules affect racial distribution of organs, and how do they affect survival? What are the effects of allowing patients to be put on waiting lists at more than one transplant center? The many questions that may be asked of the transplantation data are to some degree controlled by how the data themselves are gathered and arranged.

It is the goal of this article to further understanding of the way transplantation data are collected and organized, in order to enable better interpretation of research results, more acute awareness of data limitations, and clearer concepts of how new analyses might proceed. This article is intended for an audience of researchers in the transplant community: both those who use existing research and those who create new analyses with these data. By examining the sources, quality, and organization of the different types of transplant data available, we hope to stimulate new exploratory initiatives and help researchers with study design—as well as improve the understanding of existing results.

A fundamental step in describing the data available for research on transplantation is to conceptualize the range of information available and to organize it into areas of research interest. The first section of this article previews the final research database by showing how the diverse collection of data are organized in records representing the different types of 'units of analysis' of interest to a researcher, saving a detailed discussion of the sources for each type of record for later sections. We describe how such a wide range of sources is reorganized from their original format suiting their original purposes—mostly organ allocation but also Medicare billing, Social Security Administration benefits, etc.—to a format better adapted to the support of research questions. Just as is the case in designing a research database, it is useful to begin describing this database by considering how the table organization will facilitate answering a series of interesting research questions.

The remaining sections of the article describe the sources of the underlying data, how they are collected, and how they fit into the framework outlined above. In the second section, we focus on data collected by the OPTN for the purposes of both organ allocation and transplantation research. This section focusses on the historical and technical development of these data collection systems, with an emphasis on how changes and quality control measures in these systems have improved the quality of data available. In this discussion we hope to acquaint researchers with the particular strengths and weaknesses

present in many of the primary data elements. We also point out the context in which these data were originally collected, which may be different from how they are used for research.

In the final section of the article, we describe in more detail the 'secondary' data sources incorporated into the research database used by the SRTR. These secondary sources are used to augment the primary data reported by OPTN members, both to improve the quality and to expand the scope of the data. We describe some of the sources available, and examine their impact on answering several research questions.

Further discussion of the types of analyses supported by these data can be found in 'Analytical Approaches for Transplant Research' (1), a companion article in this supplement, as well as in Appendix H of the 2002 OPTN/SRTR Annual Report.

Organizing Data for Research

Data structure and units of analysis

This section describes the organization structure of many sources of data assembled for transplantation research. Though the examples here are taken directly from the SRTR, they are generic in application: They might resemble data organized for similar purposes by the OPTN or any other researcher who obtains these data from either the SRTR or the OPTN.

We should first review some terms used to describe data organization. Data are arranged into separate 'tables', often SAS or SPSS datasets or SQL tables. Each of these tables, which are 'relational' in that they may be linked one to another, contains a series of rows or records, each representing one item of interest such as a person, transplant recipient, or organ. Each column, known as a field or variable, represents a different characteristic of that record. In a table describing transplants, for example, these columns include such things as age at transplant, type of organ, and information about the transplant center; in a table describing each organ available from a deceased donor, these fields might include the eventual disposition of the organ, how many candidates refused the organ, or the reason that it was not recovered.

The roles in the 'relationship' between two tables are often described as 'parent' and 'child': for each record in a child table, there is a linked record in its parent table. There may, however, be some parent records with no child records, while other parent records have many child records. For example, in the relationship between a transplant (parent) and transplant follow-up (child), a transplant may have no follow-up forms filed, or one, or two, or 10; yet all follow-ups must be linked to one and only one

transplant. Extensive parent-child organization is useful for maintaining data integrity in applications that keep track of constantly changing values, such as the OPTN organ allocation procedures, though it may make research with these data computationally intensive.

Instead, when preparing analysis files, consideration is given to the 'unit of analysis' that may be of interest to the researcher. Different tables are organized for different research questions, using different units of analysis as rows in each table. More emphasis is placed on creating a table where a single record carries a wide variety of information about a record of inherent interest to the researcher, and less consideration is given to the efficiency of data storage, waiting list management, or allocation matches. Data from many sources and related tables may be summarized and attached to the record of interest. For example, many researchers want to examine transplants (unit of analysis) and their post-transplant survival, such as Tables X.9 in each organ-specific section of the data tables in the Annual Report. A table in which each row represents a transplant may be augmented with data summarized from the related tables of follow-up sources, such as each recipient's latest status as alive or dead and the date of that status. A table in which all of this information is summarized on a single record is easier to analyze than assembling information from multiple parent and child rows in multiple tables. However, for other purposes, such as counting immunosuppressive medications during follow-up periods, it may still be useful to use individual records for each follow-up period. Figure 1 shows a useful scheme of organizing these data into a 'record of interest', drawn from the example implemented for analyses by the SRTR. This figure also gives an idea of the breadth of commonly used units of analysis and the relationships between them.

One central organizing element in this structure is the Person Linking Table (PLT), in which each record is a person—perhaps a living donor, transplant candidate, or transplant recipient. The PLT facilitates a common patient identifier to be assigned to records in all other tables, linking persons on the basis of Social Security numbers (SSNs), names, dates of birth, and other person-level information, while accounting for many of the mistakes in entering these fields. The maintenance of this identification roster, with aggregated identification information compiled from all data sources, has two primary functions. First, it facilitates a system of matching to both external data sources and other records within OPTN data, such as for persons who receive multiple transplants or even for donors who later become recipients. Second, the common patient identifier provides an anonymous means of person identification for researchers without revealing names or SSNs. The matching system is described in greater detail below.

The other table entities in Figure 1 relate to a specific subject of interest for research: candidacies, donors,

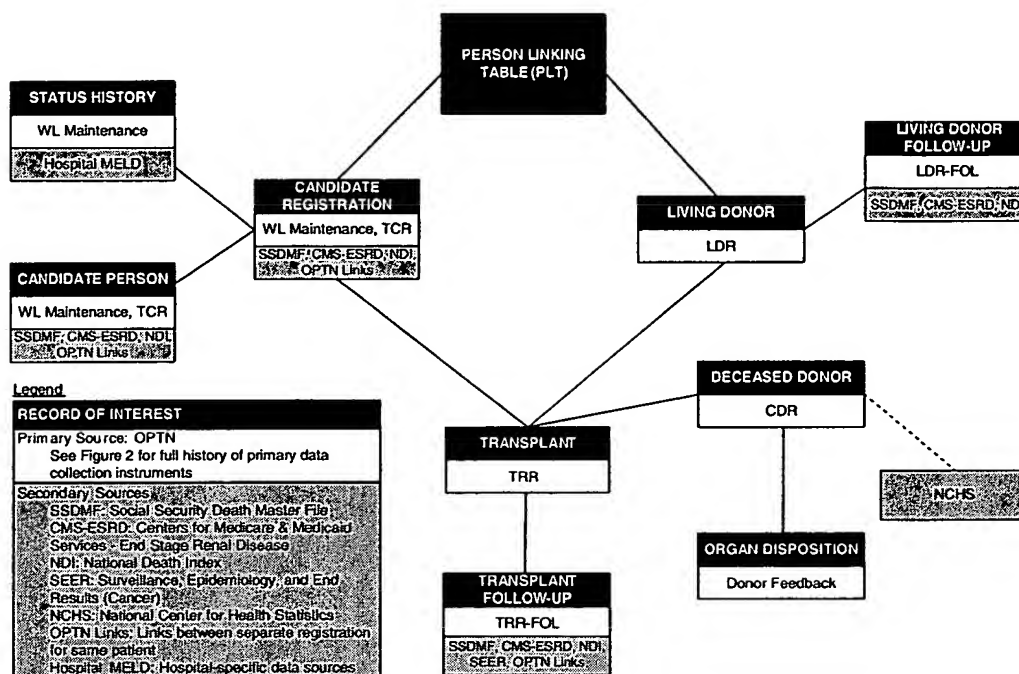


Figure 1: Transplantation research data organization, primary and secondary sources. Source: SRTR.

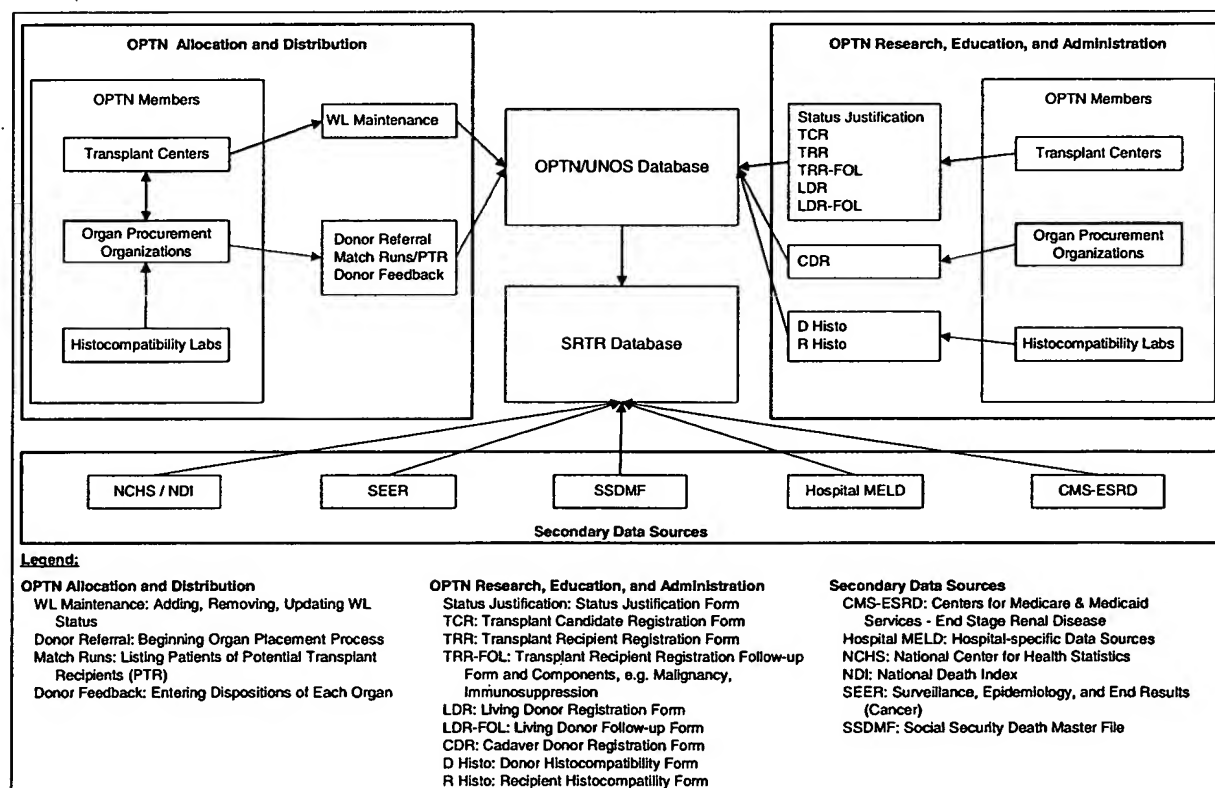


Figure 2: Data submission and data flow, primary and secondary sources. Sources: SRTR and OPTN.

transplants, and the components thereof. In addition, this figure documents some of the primary and secondary data sources which may contribute to each table. Further detail regarding the specific data collection instruments for the primary data collection by the OPTN is shown in Figure 2.

Analysis tables

Though the PLT is useful for keeping track of summarized person-level information and matching to newly incorporated records or data sources, it is often not directly useful for analyses. Instead, using a common patient identifier, data from this table are added to separate tables more closely based on 'units of interest' for analyses such as the following:

- transplant candidates (e.g. waiting time, mortality on the waiting list);
- transplant recipients (e.g. graft survival, complication rates, incidence of tumors);
- donors (e.g. donation rates, donor characteristics that influence graft survival, etc.).

Each of these, in turn, has its own child tables as well as both primary and secondary sources of data. Later in this article we discuss, in more detail, the primary data collection methods and secondary data sources for these tables.

Analysis tables: candidates

'Time to Transplant' tables, the second in each of the organ-specific data tables sections of the Annual Report, make use of a unit of analysis that represents a candidate registration. Such a table may also be useful for measuring mortality on the waiting list, either at the center-specific level or for comparison to post-transplant mortality in evaluating the efficacy of transplant for a given patient.

The 'candidate registration' table includes persons who are registered on the OPTN waiting list as well as additional candidates who have received a living donor organ, even if they have never been placed on the waiting list. The vast majority of candidate information comes from the candidate registration and waiting list information collected by the OPTN. This table presents information about candidates during the time they are waiting to receive an organ, such as the center at which they are listed, when they are listed, factors affecting organ allocation like blood group or medical urgency status, and when they are removed from the list and for what reason (death, transfer to another center, transplant, etc.). Often, fields in the operational data are transformed to more closely reflect events of interest for analyses. For example, to facilitate time to transplant analyses, waiting list removal dates for transplants are set to the transplant dates when the candidates cease to be eligible for allocation—though in practice a patient may be removed from the waiting list at any time from the date an organ is allocated until days after it has been transplanted.

As Figure 1 indicates, the candidate file is primarily based on data that are entered as part of waiting list maintenance by the transplant centers, as well as the Transplant Candidate Registration (TCR) Form. These data may also be augmented with data from other data sources as described below. Most notably, additional mortality sources are very important, because transplant programs are not required to track and report outcomes after removal from the waiting list (other than removal for transplant). These sources may include the Social Security Death Master File (SSDMF), Centers for Medicare and Medicaid Services data on End-Stage Renal Disease patients (CMS ESRD) for kidney and kidney-pancreas patients, and the National Death Index (NDI).

Some analyses make use of candidate data recorded at a narrower level than the usual record of interest. For example, the first relational 'child' table shown connected to the candidate file is the waiting list 'status history' table: for each registration on the waiting list, at least one record exists in the status history table. This table records characteristics that may change during the course of waiting list tenure, such as medical urgency status or Model for End-Stage Liver Disease (MELD) score for liver candidates. Each record in this table is associated with a time at which those characteristics began and ended. Such a file is useful for finding a patient's status on any given day, calculating the accumulated time at each status at any point in time, or examining how trends in a patient's MELD score might affect mortality. From an organ allocation perspective, on the other hand, only the current urgency status and a running total of time accumulated at (or above) each status are important. The status history analysis table is created by examining histories of changes to the operational waiting list that are recorded as part of the audit process in the operational organ-allocating database, noting all changes that involve status, and augmenting this file with nonoverlapping start- and end-dates for the span of each set of characteristics. Therefore, an analyst may move through this file in a temporal fashion for each patient, examining current status for each patient and facilitating a time-dependent model such as one that associates status on a given day with outcome (mortality or transplant) on the same day.

The status history file is a highly focused accounting of the candidate file; the 'candidate-person' table, conversely, aggregates candidate records into a much wider view based on individual persons. In the first candidate table described, and for the purposes of organ allocation, a person is given a registration record each time he or she is entered onto a waiting list at a transplant center; a given person might have several registrations, either in sequence or concurrently. By using the common patient identifier, one can construct 'candidacies' that span registrations, separated for each person only by transplants. A candidacy in this file starts from the time a patient is first put on the waiting list at any center and ends when that

patient receives a transplant (from a living or deceased donor) from any center, is removed for the last time, or dies. A second candidacy might begin for the same patient when he or she is relisted after a failed transplant. The candidate-person table also has a status history sub-table, whose records have similar information and purpose to the status history child table of the registration-based candidacy file, but with the additional function of reconciling differences between status recorded for different listings and summarizing the number of concurrent listings at any point in time.

The candidate-person approach is consistent with an 'intent-to-treat' analysis. In such an approach, the original goal of any wait-listing is to transplant the patient, doing so at any center is a success for that patient, and the 'waiting time' that a patient cares about is the time from his or her first listing until transplant. By contrast, the registration-based candidacy table may be more relevant when evaluating a center's ability to move a patient through the waiting list process.

Analysis tables: transplants

A subset of the candidate registrations make their way into the transplant table, including persons who have received a transplant from the waiting list as well as those receiving a living donor transplant. The transplant file is used by analysts wishing to characterize trends in volume and characteristics of patients receiving transplants (Table 4 in the organ-specific data tables sections of the Annual Report), as well as analyses examining post-transplant survival (Tables 8 and 9, Graft and Patient Survival).

This table draws primarily upon information from the Transplant Recipient Registration (TRR) Form, filed by centers following each transplant. The table includes characteristics of the patient at the time of transplant and the transplant operation itself. For ease of analysis, characteristics of the donor are added, as well as donor-recipient interactions, such as calculated HLA mismatch scores, blood compatibilities, and whether the organ was 'shared', based on the relationship between the organ procurement organization (OPO) recovering the organ and the transplant center.

The primary transplant table also includes summarized information from the child table 'transplant follow-up'. Data in this table come from the post-transplant follow-up forms collected 6 months after transplant (except for thoracic organs) and then at each yearly anniversary. These follow-up forms contain items such as hospitalization, current lab values, functional status, and other developing medical conditions. This table, in turn, has specific sub-tables of its own, recording details of immunosuppression treatments and developing malignancies, for example.

The data gathered during the organ allocation process and follow-up forms are strengthened further: Similar to the candidates table, several secondary follow-up sources pertaining to death, graft failure, retransplant, and resumption of dialysis are summarized and added to the transplant table, as described in Figure 1. These important elements, and their ramifications for data completeness, are described later in this article.

Analysis tables: donors

Donor information is shown separately for living and deceased donors—not only because such different primary information is collected by the OPTN for each group, but also because each relates to its own set of secondary data elements and its own analyses. Indeed, much of the donor information that is common to both types of donors and useful for analysis of transplant outcomes has already been added to the transplant file itself. The donor files might be more frequently used for such things as analysis of organ disposition and reasons for nonrecovery of organs from deceased donors, or for examining the post-donation outcomes of living donors.

For each deceased donor, up to 11 whole organs or organ segments may be recovered (one heart, two kidneys and lungs, and up to two segments each for pancreas, intestine, and liver). This recovery information is stored in a sub-table of the deceased donor table, 'organ disposition', giving reasons for nonrecovery or nonconsent, and eventual disposition of each organ. The information from this table is taken directly from forms filed by OPOs. The third section of the data tables details disposition (e.g. local transplant, shared transplant, used for research), reasons for nonuse, and reasons for nonrecovery of organs. Analysts might also use such a table to glean additional information regarding unused organs or might wish to examine organ recovery data available in OPO-specific format.

In addition to organ disposition data, researchers may combine deceased donor information with external sources of mortality data for the general population such as information from the National Center for Health Statistics (NCHS). Combining such sources allows researchers to compare availability of potential donors in certain areas to the number of organs recovered, or to evaluate successful methods used to obtain family permission for organ recovery. The use of OPO forms and NCHS data is discussed below.

Living donors are also included in the PLT, to facilitate matching with internal and external data sources, and allow for additional ascertainment of events such as death, dialysis, or registration on a waiting list. For living donor follow-up, transplant centers are asked to report at 6 months and 1 year, though compliance and reliability are not as good as they are for recipient follow-up. Many centers submit follow-up forms for living donors as required, but are less likely to see these donors, who are

often healthier or live elsewhere and may therefore be more difficult to track. For living donors from 2000, though 90% have an appropriate 1-year follow-up form filed, 42% of these living donors are coded as 'lost to follow-up'—indicating that, even when complying with OPTN follow-up requirements, centers do not know what has happened to these patients.

Though possible secondary data sources are listed (SSDMF, CMS ESRD, NDI), lack of completeness and accuracy in living donor identification information jeopardizes the use of these external sources. Before April 1, 1994, SSNs were not collected for living donors. Since then, more than half of SSN matches to the SSDMF are highly improbable (based on review of names and implausible relationships among birth dates, death dates, and dates of organ recovery), indicating that there is probably significant inaccuracy in these identifiers even when they are available.

Primary Data: The OPTN Data Collection System

Data system components

The OPTN data collection system and database were developed in 1986 by the United Network for Organ Sharing (UNOS, the OPTN contractor) after the 1984 National Organ Transplant Act called for the creation of a national network for organ sharing and a scientific registry to monitor the clinical progress and effectiveness of transplantation. The information systems themselves have undergone many changes with regard to technology, data collection processes, and data content. The system consists of three components: the national transplant waiting list, the donor-recipient match process, and the data collection 'forms'. The first two together can be thought of as the allocation data, as these are the data essential for the day-to-day operation of distributing organs to potential recipients. The 'forms', collected with somewhat less urgency, are intended more for research and administration purposes.

Figure 2 shows data flow into both the OPTN and SRTR databases, focussing on the different mechanisms for submission of data by OPTN members to the OPTN database. The figure shows data separated into two types: that used for organ allocation, on the left, and that used for research, education, and administration, on the right. This figure also serves as a full list of the major data collection instruments in place for OPTN members. Copies of the forms may be found in Appendix I of the *2002 OPTN/SRTR Annual Report*.

The initial process of data collection, as well as organ allocation, begins with the waiting list. At the time a patient is placed on the waiting list, essential data are captured for donor matching and allocation. Such data have always included such variables as blood type and

medical urgency status. These data can and, in some cases, *must* be revised and updated by personnel authorized to access the waiting list. Although the transplant program controls the list for its patients, it may authorize the OPO or even the histocompatibility laboratory to perform maintenance on it. Adding a patient to the waiting list prompts the generation of the TCR, which is sent to the transplant program to collect additional information about the candidate that is used for purposes other than matching and allocation.

The donor-recipient match process begins when an OPO enters a donor into the system. Donor data essential for matching and allocation are captured and a 'match run' for each organ type available (e.g. kidney, heart, etc.) is generated. This programming accomplishes several functions simultaneously: it reflects organ distribution and allocation policies in place at the time of the match, identifies all patients that are clinically compatible with the donor, assesses their geographical appropriateness based on donor location, and assigns priority rankings. The product is a match run for each organ type, available electronically and in printable formats to the OPO for organ placement. If authorized by the OPO, a histocompatibility lab may run a match in lieu of the OPO.

There are several subsystems within the donor-recipient match process that collect data and generate donor forms. At the time of the match, the Potential Transplant Recipient (PTR) Form is created on the match run itself. This data form is made available for the OPO to record the refusal reasons (such as donor quality, recipient unavailability, or positive crossmatches) for potential recipients ranked higher on the list than the ultimate recipient(s). This information is provided by the OPO based on organ offer responses from transplant programs. Transplant centers may then validate, via UNet, the refusal reasons entered by the OPO during a 15-day period after the match is completed by the OPO.

The OPO is required to report the results of donor organ placement efforts through a process called 'donor feedback'. Upon completion of the donor feedback (itself a set of forms), the Cadaver Donor Registration (CDR) and Donor Histocompatibility (DH) Forms are generated to gather donor data for research and reporting purposes. OPO personnel complete and return the CDR forms, while the tissue-typing laboratory serving the donor hospital provides data requested on the DH form.

Transplant recipients must be removed from the waiting list within 24 h of receiving an organ. This completes the 'recipient feedback process', and two additional forms collect additional research and reporting information: the TRR Form, completed by the transplant program, and the Recipient Histocompatibility (RH) Form, submitted by the recipient center tissue-typing laboratory. When a hospital reports a living-donor transplant for a patient who was

not on the waiting list, a TCR, TRR, and RH form are generated for the recipient. A Living Donor Registration (LDR) and DH Form are generated for the donor. The transplant program completes the recipient forms and the tissue-typing laboratory completes the histocompatibility forms. The Living Donor Follow-up and Transplant Recipient Follow-up Forms are generated and transmitted to the transplant program 6 months after transplant and every 1-year anniversary of the transplant. If a post-transplant malignancy is reported on a follow-up form, a Post-transplant Malignancy Form is generated and sent to the transplant program. If a patient is reported as retransplanted, dead, or lost to follow-up, no further follow-up forms are generated for the specific transplant event. If a pancreas or kidney graft failure is reported, then follow-up on the patient is continued for only 2 more years. For all other organs, no further follow-up forms are generated.

Data collection forms submitted by transplant programs are completed by a variety of hospital employees, including nurses, clinical coordinators, clerks, and administrative assistants. A hospital's 'data coordinator' can be any of these types of personnel. Since the inception of the OPTN database in 1986, financial pressures on hospitals have increased, as has the volume of data forms for most hospitals. Some programs devote significant resources to OPTN data submission activity; others less so. The implications of budgetary pressures for data quality have been a primary concern of the OPTN/SRTR Data Working Group and the OPTN Data Advisory Committee, two new committees supporting data-related OPTN process and policy development. During a comprehensive 2-year process since the fall of 2000, these committees have been able to significantly streamline and reduce the amount of data to be collected by the OPTN. Final changes will be implemented once approved by the OPTN/UNOS Board and the Federal Office of Management and Budget. It is hoped that a lower data burden at the facilities will lead to higher quality for a smaller amount of data, focusing on the most scientifically relevant items.

History of the data collection system

Figure 3 shows some of the evolution of the OPTN/UNOS data systems. UNetSM, an Internet-based application for waiting list maintenance, donor-recipient matching, and forms-based data collection for research and administration, was implemented on October 25, 1999. Before UNet, the most significant modifications to the data system occurred in 1990 and 1994. In 1990, the waiting list and data forms systems were converted from a flat file data system to a relational database, making the data easier to manage with regard to both storage and analysis. Based on almost 7 years of use, analysis, and reporting by the OPTN/UNOS committee system, the UNOS staff, and the Federal Government, a large number of data elements were added to the data collection forms. These additions required a second database conversion in April 1994. All

OPTN/UNOS committees provided input during the forms revision process. Since that time, an incremental process of adding data fields has resulted in gradual increases in data volume.

In 1996, UNOS created a client-server application on a Lotus Notes platform called Tiedi[®] (transplant information electronic data interchange) to collect transplant data electronically rather than on paper. This was the first effort to transfer to OPTN members the ability to maintain the submission of their own data collection forms and to eliminate the need to mail paper forms to UNOS. With this system, as many as 50% of centers and laboratories were using Tiedi for data submission. Since its use was not a required method of data submission, some stayed with the existing paper-based submission and manual data entry system.

When UNOS implemented UNet in 1999, the degree of security increased significantly, requiring user-specific passwords and encryption for all patient-identified data transmission. An on-site UNet security administrator assigns access privileges and controls user access at each hospital. All data are now transmitted via the Internet with secure socket layer (SSL) technology and 128-bit encryption. As well, the utilization of electronic submission of data among members has increased greatly: currently, 3 years following the implementation of an Internet-based data system, 97% of OPTN centers, laboratories, and OPOs enter their research and administration forms electronically.

UNet has tightly integrated all three components of the data system. The waiting list and the forms databases were combined into a single longitudinal relational database (Microsoft SQL Server), and the data systems were no longer parallel and compartmentalized but seamlessly integrated. Within 6 months, the percentage of OPTN members using the new system to access and manage the waiting list increased from an estimated 40% to more than 90%. Currently, all waiting list management is performed on UNet (mostly by transplant center personnel) rather than by requesting changes by phone through the UNOS Organ Center.

For certain wait-listed patients, waiting list data management is not only available to the hospitals but in some cases is *required* in order to avoid automatic allocation status downgrades. For example, a patient listed as liver allocation Status 1 must be recertified weekly for that status by the hospital, on the basis of current laboratory data. Additionally, since July 8, 2002, status justification forms for liver and heart (Status 1A and 1B) must be submitted through the UNet system.

Before UNet, the donor-recipient match run yielded a computer-printed data list. With the implementation of UNet, the match list became a data file from which data

	1986-90	1990-94	1994-96	1996-99	1999 to Present
	Pre-OTIS		OTIS	OTIS + Tiedl®	UNet SM
Waiting List Management					
Communication	Phone to Organ Center with paper back up and validation. Some facilities use terminal emulation via modem				Member online (Web-based)
Donor-Recipient Matching					
Communication	Terminal emulation and modem or phone to organ center and faxed to OPO				OPO generates online (Web-based)
Data Collection Forms					
Mode of submission	Paper. Manual data entry at UNOS. Line prompt entry			Electronic forms added	Web-based submission. Paper forms phased out
Submission prompting	Member- initiated	Electronic events prompt form generation. Forms mailed by UNOS			Electronic events prompt blank web-form generation
Edit checks	Few		Checks added over this period, data verification reports by mail		All fields validated electronically. Verification reports by mail
System					
Storage system	VMS flat files	VMS relational database	VMS relational database, Lotus Notes		Microsoft SQLServer Relational Database
Component integration	None		Match and forms linked. WL addition initiates TCR		All systems completely integrated
Security	One password per center. No encryption during transmission				User-specific passwords. Full 128-bit encryption

Figure 3: OPTN/UNOS data system evolution. OTIS = Organ Transplant Information System, Tiedi = Transplant Information Electronic Data Interchange, UNet = Internet-based data collection system. Source: OPTN.

variables could later be extracted for analysis. This change also allowed the OPTN to integrate PTR data with the match output. Another advantage of UNet is that matches for all organ types can now be run simultaneously—rather than serially—as was necessary on the previous mainframe computer system. The flexibility of match runs that are files rather than printed lists had allowed OPOs to view, print, and export matches as data files that can be stored in databases at the OPOs and in the OPTN data system.

With regard to data submitted on forms for research and administration (e.g. TCR, TRR, and TRF Forms), the transition to an Internet-based system has had a number of implications. Forms are generated and appear as 'expected forms' when the member is in UNet. The member can complete the electronic forms manually or import data from a local electronic records system. UNet forms include fewer text fields than the paper forms did, utilizing pick-lists and reducing the need for visual edit checks in these fields by UNOS data quality staff. Most other fields have programmed acceptable responses and standard data ranges. Immediate edit checks and cross-field edits for some variables reduce data errors by allowing the data collector to pay immediate attention to problems as the data are entered. Forms cannot be electronically marked as 'validated' (complete) until all fields have been entered and have passed a series of edit checks. Data quality has become largely the responsibility of the system and of OPTN members, and submission via UNet has eliminated the mailing back and forth of paper forms containing erroneous or incomplete data.

Measures of internal data quality

The quality of the data within the OPTN database is affected by the timeliness, completeness, and accuracy of the data submitted by members. Also pertinent in any discussion of quality is whether the variables collected are sufficient and appropriate (and not superfluous) for the needs of the OPTN, the SRTR, the Federal Government, and the public. These measures of data quality are currently being evaluated by a new committee, the joint OPTN/SRTR Data Working Group. The most recent OPTN and SRTR contracts required that such a committee examine data quality in detail and advise the OPTN/UNOS Data Advisory Committee and Board on necessary revisions. Other aspects of OPTN data quality are addressed by activities of the SRTR, internal operations at UNOS, and the OPTN data submission policy compliance process.

Approaches to improve data timeliness and completeness

Until June 30, 2002, OPTN data submission policies required that 99% of data forms due from an OPTN member be submitted within a year of the dates they were expected. In most cases, the expected date for a form was 60 days after it was generated (e.g. transplant date or transplant anniversary). In an effort to improve the timeliness of data collected by the OPTN, the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services included in the current OPTN contract a requirement that 100% of each program's data be complete within 6 months of the

Table 1: Transplant Recipient Follow-up (TRF) form submission at 1 year after form generation, by transplant program type and volume

Organ and program volume*	No. of programs	Percentage of TRF forms submitted within 1 year of expected date				
		0%	1–33%	34–66%	67–99%	100%
Heart						
Low (0–9)	44	0.0%	4.5%	6.8%	29.5%	59.1%
Medium (10–17)	44	0.0%	6.8%	4.5%	40.9%	47.7%
High (18+)	42	0.0%	11.9%	9.5%	57.1%	21.4%
Total	130	0.0%	7.7%	6.9%	42.3%	43.1%
Kidney						
Low (0–24)	78	1.3%	6.4%	7.7%	32.1%	52.6%
Medium (25–59)	83	1.2%	6.0%	6.0%	41.0%	45.8%
High (60+)	83	0.0%	6.0%	13.3%	45.8%	34.9%
Total	244	0.8%	6.1%	9.0%	39.8%	44.3%
Liver						
Low (0–21)	37	0.0%	5.4%	16.2%	35.1%	43.2%
Medium (22–45)	39	2.6%	7.7%	10.3%	35.9%	43.6%
High (46+)	39	2.6%	10.3%	2.6%	38.5%	46.2%
Total	115	1.7%	7.8%	9.6%	36.5%	44.3%

Source: OPTN database. *Transplants performed in 2000.

form's expected date. The OPTN/UNOS Board approved this policy change in November 2001.

Table 1 shows transplant centers' compliance with the follow-up data submission policy in place before June 30, 2002. These results are stratified by the volume of transplants performed at each program in the previous year. The data show a number of high-volume programs in compliance with the previous policy. For example, 83 high-volume kidney programs (35%) submitted their year 2000 follow-up forms within a year of their expected dates and, as such, had perfect compliance. Although some low-volume programs show poor compliance, there is a slight tendency for smaller programs to have better compliance with follow-up policies. In response to concerns that the accuracy of publicly reported program-specific survival rates may be affected by incomplete outcomes data in the OPTN database, the SRTR has undertaken an effort to obtain missing OPTN outcomes data from other sources, as described below. Overall, 87% of TRFs were submitted in compliance with policy, as shown in Table 2. In contrast, nearly 95% of RH forms generated in 2000 were submitted on time. OPTN member compliance with data submission policy is an area of increasing focus for the UNOS Policy Compliance Department and the OPTN/UNOS Membership and Professional Standards Committee, which is exploring more direct means to ensure compliance.

Approaches to improve data accuracy

Monitoring the accuracy of data in the database involves edit checks during the data entry process, internal processes at UNOS, and a collaborative effort of the OPTN and the SRTR. The UNOS Help Desk takes calls from members who find inaccuracies within fields that can

only be modified by UNOS staff (e.g. transplant dates and SSNs). UNOS also creates computer programs that search for inconsistencies in the database and generate discrepancy reports. For example, one program compares data entered into the age, height, and weight fields for each patient, looking for cross-field entries that seem unlikely or impossible. Other such programs compare entries for employment status, education, and age, and check patient functional status for consistency with medical urgency status. In addition, the SRTR delivers similar discrepancy reports to the OPTN each month to raise further data quality issues. When problems with records arise, data quality specialists resolve them through UNet and direct contact with transplant centers. Problems that affect a large number of records can sometimes be resolved through programmed edits, but other fields must be addressed individually. Fields in which UNet allows incorrect data entry are identified on an ongoing basis, and UNet edit checks are regularly revised to reduce opportunities for data entry errors. Recent efforts to detect database problems have included 22 different discrepancy reports and 38 different database checks. Some of these reports and checks are rerun on a regular basis to correct recurring errors. Others involve one-time projects to resolve problems, such as those related to previous database conversions or modifications.

Database checks performed to detect problems in the data have included checks among living-donor and recipient records for invalid SSNs (e.g. strings of 0s or 9s sometimes used when SSNs are unknown at the time of data entry) and checks for inconsistent entry of date of birth, race, gender, and blood type across records for patients wait-listed at multiple transplant programs. Other checks have included searches for persistent waiting list registrations when programs have reported

Table 2: Data submission compliance rates, by form type, for forms generated during the year 2000

Form type	No. expected	No. received in compliance	Compliance rate
Transplant Candidate Registration (TCR)	46 199	41 761	90.4%
Transplant Recipient Registration (TRR)	26 073	23 320	89.4%
Transplant Recipient Follow-Up (TRF)	172 448	150 014	87.0%
Living Donor Registration (LDR)	6096	4939	81.0%
Living Donor Follow-Up (LDF)	2294	1739	75.8%
Post-transplant Malignancy (TMR)	628	628	100.0%
Cadaver Donor Registration (CDR)	12 817	11 872	92.6%
Recipient Histocompatibility (RH)	23 004	21 815	94.8%
Donor Histocompatibility (DH)	13 316	12 454	93.5%

Source: OPTN database.

patients as having been transplanted and searches for transplant records when waiting list registrations have been removed for reason of transplant. With the addition of a number of new features and data entry checks in UNet, many types of database checks are no longer necessary. This has resulted in more efficient use of time for staff and in improved data quality.

In addition to a number of special discrepancy reports generated through the UNet application and sent via UNet to OPTN members for problem resolution, the OPTN also generates and prints a number of reports that it mails to each member. These mailings include a monthly summary of the member's overdue forms, a monthly list of the member's reported living-donor transplants, and semiannual confirmation reports of transplants, living-donors, and deceased donors. Each member also receives an annual report of its data submission compliance rates, according to form type. Some aspects of data accuracy cannot be addressed by electronic data entry edits, programmatic data checks, or efforts to ensure compliance with data submission policies. Experience with OPTN data suggests that certain variables within the database may be more reliable than others. In an effort to learn more about the difficulties of providing accurate data for certain fields, UNOS staff have conducted preliminary on-site transplant program audits using actual patient charts to check the accuracy of information provided to UNOS. Results of the audits suggest that data variables involving objective information readily available in medical charts and requiring little or no interpretation (e.g. race, age, and gender) tend to be highly accurate. Other types of information (e.g. patient education level, employment status, and functional status) are more difficult to find in the charts. Results of various serological tests of interest to the OPTN are largely available in the charts, but details regarding testing methods and timing of the test in relation to the transplant procedure, also of interest to the OPTN, are more difficult to interpret from the chart. Such observations by UNOS staff and OPTN members alike are being factored in as the Data Working Group and Data Advisory Committee consider data collection revisions.

Secondary Data Sources

Reasons for additional sources

Other sources besides the data collected by the OPTN provide important information that may be linked to these data or used in conjunction with them. Additional data sources help determine the areas of weakness in compliance and accuracy of the data collection described above; they can also expand the scope of available research. For example, additional data sources can help researchers perform the following important tasks:

- Ensure complete ascertainment of mortality and graft failure, improving precision of analyses and answering questions about the quality of transplant data submitted by a transplant center.
- Expand measurement of events not collected by the OPTN, such as death after a candidate is removed from the waiting list.
- Provide additional ascertainment of other events, such as malignancies from local cancer registries across the country.
- Offer measures of potentially available donors for evaluating donation practice patterns.
- Establish correlations between measures not concurrently used in organ allocation, such as between the four medical urgency status groups used before 2002 (1, 2A, 2B, 3) and the more continuous computed MELD scores for liver recipients used since then.

The PLT and patient matching

The SRTR-ESRD PLT was developed by the SRTR to provide a central repository for patient identifying data from various sources and to provide a common patient identifier that can be used to link patient data across those sources. The records in the PLT include persons found in primary OPTN data, as well as those found in Medicare data about patients with ESRD. There is a large overlap in the population covered by these two databases, as kidneys account for about two-thirds of the transplant

candidates and recipients in the SRTR database. Because most ESRD patients qualify for Medicare benefits, most kidney transplant recipients and candidates (usually on dialysis) also are found in the CMS ESRD data.

The development of the PLT was a collaborative effort of University Renal Research and Education Association (URREA) and the Kidney Epidemiology and Cost Center (KECC) of the University of Michigan. HRSA, the agency that oversees the OPTN and SRTR, and the Centers for Medicare and Medicaid Services (CMS) have an inter-agency agreement for sharing organ transplantation data. Under this agreement, CMS discontinued its separate collection of kidney transplant data, the OPTN became CMS's source for transplant data, and HRSA gained access to the Medicare ESRD data. Since 1988, first as the United States Renal Data System (USRDS) and then under various CMS contracts, KECC has developed and maintained a database that integrates almost all of the CMS data on ESRD patients. URREA and KECC, as the SRTR, have integrated transplant patients into this common database by matching to existing patients where applicable, and by adding records for transplant patients not already in the ESRD portion of the database.

The PLT data are organized around people, rather than around organs, diseases, or events. These people are the set of donors and candidates; some candidates become transplant recipients, and some donors may become candidates themselves. At the basic unit of a person, the SRTR assembles information from a variety of sources:

- candidate, donor, and transplant information (including follow-up) collected by the OPTN;
- mortality and dialysis information from CMS for ESRD patients abstracted from institutional and physician/supplier claims, medical evidence forms, and death notifications;
- death information from the SSDMF;
- death information from the NDI.

To handle incomplete or erroneous identifiers in the diverse data sources used, patients are added to the PLT using a 'fuzzy' matching system that considers SSNs, names and nicknames, dates of birth, and other identifying information (e.g. gender, transplant dates, and death dates)—all with allowances for common coding mistakes such as transpositions or entry of the wrong birth year. For example, the first two records listed in Table 3 would be linked as the same person because of the similar name and SSN, along with date-of-birth evidence. However, the third person, perhaps a family member using the same Medicare billing number, receives a distinct patient identifier on the basis of conflicting evidence, despite having the same SSN and last name.

Table 3: Sample records for sorting into PLT

Name	SSN	Date of birth	Source	Person_ID
Joe Smith	123-45-6789	03-06-1968	KI candidate	1
Joseph Smyth	123-46-5789	03-06-1968	Living KI recip.	1
Lynda Smith	123-45-6789	05-12-1965	KI donor	2

Source: SRTR.

Ascertainment of graft and patient survival

The most important use of additional data sources has been in investigating the completeness of mortality data reported by transplant centers to the OPTN. In recent years, the reliability of such figures as the center-specific post-transplant survival calculations published by the SRTR has been called into question (2,3) because some centers have had poor return rates for post-transplant follow-up forms. Complete ascertainment of mortality is imperative for comparing post-transplant outcomes to the outcomes of those on dialysis or the waiting list. It is important to use multiple sources because no single data source is complete by itself, and because data submitted directly by transplant centers are subject to bias in reporting, either toward or away from sicker patients. For example, a center might have more contact with sicker patients, thus making it easier to report on them; on the other hand, it is possible that some centers could lose track of these patients more easily—or some might even attempt to 'fool the system' by underreporting patients with poor outcomes.

Linking within OPTN data

Although this is not a data source that is 'external' to the OPTN data collection system, a modification to the data from the structure established for organ allocation can be useful for research. This modification is made possible by the central organization of a patient record and common patient identifier in the PLT table. Within the organ allocation and data collection database, each waiting list registration and transplant is treated as a separate entity, as linkage is not necessary for allocation.

For patients with multiple waiting-list candidacies or multiple transplants, crucial data such as the patient's death date may be reported for only the last candidacy or transplant. The common patient identifier allows data for the same patient to be linked together within the SRTR database. For a patient with multiple transplants or candidacies, this allows a death date reported in follow-up for the last transplant or reported on a final candidacy after graft failure to be made available when analyzing any of the previous transplants. Within the OPTN database, linkage across multiple listings or transplants is accomplished primarily through SSN.

SSDMF

The SSDMF, publicly available from the Social Security Administration (SSA), contains over 70 million records

created from reports of death to the SSA. Records are reported for both beneficiaries and nonbeneficiaries; 90% are reported by family members and funeral homes, the remainder are reported by state and federal agencies, banking institutions, postal authorities, etc. This file includes the following information on each decedent: SSN, name, date of birth, date of death, ZIP code of last residence, and ZIP code of lump sum payment. Because it may miss some nonbeneficiaries, the absence of a particular person in this file does not prove the person is alive, and the deaths of children are more likely to be missing. Of the deaths included in the SSDMF, more than 98% are complete by the end of the third month after a death date.

Every month, the SRTR adds new information from the SSDMF into the patient table. For each patient in the PLT, the SRTR looks up the SSN for that patient in the SSDMF. When found, the names and birth dates are checked before the SSDMF death date is recorded in the patient table.

CMS ESRD database

Medicare data, described above in relation to the PLT file, provide an additional source of death data for ESRD patients. They also can provide pretransplant dialysis history and a source for inferring graft failure from return to dialysis. Because of Medicare rules, most of these data center on ESRD patients, though data can also be obtained for any patients in the PLT with failure of other organs who appear in the Medicare data.

The Renal Beneficiary and Utilization System (REBUS) system at CMS is the primary CMS ESRD database, and includes data from a number of sources that are useful in organ transplantation research. REBUS obtains death dates for beneficiaries from the Medicare Enrollment Database (EDB), as well as from the ESRD Death Notification Form, which includes the cause of death. As a source of dialysis history, the ESRD Medical Evidence Report is filed for all patients starting dialysis, certifying that a patient has ESRD and indicating the cause of ESRD and the date of first dialysis. This form may also indicate the date of a transplant, the date of return to dialysis after a transplant, and the date of death. Since 1995, dialysis facilities have been required to complete this form for all new dialysis patients, not just those eligible for Medicare.

In addition to these forms, detailed Medicare claims data are obtained separately from REBUS and are updated annually. These claims data are another source of date of death, date of first dialysis, and the date of return to dialysis after a transplant.

NDI

Compiled by the National Center for Health Statistics (NCHS), the NDI contains data from death certificate

information submitted by state vital statistics agencies. Researchers may use this file to determine whether subjects have died and to facilitate obtaining actual death certificates from the state agencies. Researchers may submit a list of subjects to NCHS, which in turn matches with the NDI using a 'fuzzy' matching algorithm similar to that described above for the PLT. Resulting match possibilities are returned to the researcher, who makes the final decision about the quality of each match.

While the NDI is the most complete source of death data used by the SRTR (missing approximately 5% of deaths in the United States), it has a number of significant limitations. First, the NDI is updated only annually. Taking into account the time for NCHS to process the death certificates and run matches, the reporting time lag is 1–2 years after the death date. Fees for NDI matching are also substantial.

A second significant limitation is a restriction on how NDI data may be used. Agreements between the NCHS and the state agencies that collect the death certificates prohibit using the data for administrative or regulatory purposes. This means that while these data may be used for national mortality figures, they may not be reported back to transplant centers or be used for center-specific reports.

The OPTN and SRTR have carried out a test of the usefulness of the NDI for supplementing and benchmarking the completeness of the OPTN death data and other available sources of death data. The OPTN prepared a file of patients for whom the OPTN has no data since 1999 and who were alive at the last known time point. This file was matched against all years of the NDI. The results of this exercise are included in the discussion of all extra mortality sources below.

Implications of secondary sources for mortality

The OPTN data alone capture most of the deaths among patients in the SRTR database, and some deaths are captured only by the OPTN data, especially when multiple records within the OPTN data are linked and considered. The SSDMF and ESRD sources provide important additional coverage at low cost. The NDI provides some additional coverage, although at higher cost and with a longer time lag. Table 4 shows the frequency of update, usual reporting lag, and cost associated with these various sources of death ascertainment. Table 5 shows the contribution made by each of these sources to the ascertainment of deaths among transplanted patients. For most patients, death dates are found in more than one source; in these cases, the sources are checked in the order in which they appear (from left to right) in Table 5:

- *OPTN Primary* (death reported with the first transplant recorded);

- *OPTN Secondary* (death ascertained from a subsequent waiting list registration or transplant);
- SSDMF;
- CMS ESRD;
- *NDI* (searched last because it is the most difficult, restricted, and expensive source).

Any patient with an 'OPTN Primary' death date is classified with that source. If the patient does not have an 'OPTN Primary' death date, then the other sources are checked in the indicated order until a date is found, and each death is attributed to only one source. For example, if a person's death date is found only in the SSDMF and CMS ESRD, then the patient is classified with SSDMF. The 'contribution' of a source is the proportion of all

Table 4: Additional sources of transplant outcome data

Source of death data	Frequency of SRTR update	Reporting lag after death	Added cost	Used in 2002 Annual Report?
OPTN data	Monthly	1–15 months after death; may not be reported until next annual follow-up form	None	Yes
CMS ESRD data	Monthly	1–6 months	None	No
SSDMF	Monthly	3 months	Low	Yes
NDI	Yearly	1–2 years	High	No

Source: SRTR.

Table 5: Distribution of deaths from 1991 to 1999 among transplant recipients by source of death date, organ, survival time after first transplant, and patient age at death

	Deaths	Source of death date				
		Primary OPTN	Secondary OPTN	SSDMF	CMS ESRD	NDI
All	45 561	77.3%	6.9%	14.3%	0.7%	0.8%
Kidney and pancreas (K/P)						
All	25 859	68.9%	6.0%	22.9%	1.3%	0.9%
Kidney	24 607	68.1%	6.1%	23.6%	1.4%	0.9%
Pancreas	69	60.9%	17.4%	17.4%	1.4%	2.9%
Kidney–pancreas	1183	87.2%	3.6%	8.8%	0.2%	0.3%
Non-K/P organs						
All	19 702	88.3%	8.0%	3.0%	0.0%	0.6%
Liver	8412	81.5%	14.6%	3.1%	0.0%	0.8%
Intestine	173	82.1%	13.3%	2.9%	0.0%	1.7%
Heart	7649	93.0%	2.8%	3.6%	0.0%	0.6%
Lung	3147	94.7%	3.1%	1.8%	0.0%	0.3%
Heart–lung	321	94.1%	4.0%	1.2%	0.0%	0.6%
Kidney and pancreas						
Died within 1 year of transplant	4504	94.1%	1.4%	4.3%	0.1%	0.2%
Died 1–2 years after transplant	2157	82.2%	3.3%	13.4%	0.6%	0.6%
Died 2–3 years after transplant	2288	76.0%	4.3%	18.1%	0.9%	0.8%
Died 3–4 years after transplant	2459	71.6%	5.4%	20.9%	1.3%	0.9%
Died 4–5 years after transplant	2370	65.5%	6.8%	25.4%	1.0%	1.3%
Died ≥ 5 years after transplant	12 081	56.0%	8.5%	32.4%	2.0%	1.1%
Non-K/P organs						
Died within 1 year of transplant	9651	90.3%	9.0%	0.5%	0.0%	0.1%
Died 1–2 years after transplant	2401	90.4%	7.4%	1.7%	0.0%	0.5%
Died 2–3 years after transplant	1737	88.7%	7.8%	2.8%	0.0%	0.7%
Died 3–4 years after transplant	1437	88.4%	6.4%	4.6%	0.0%	0.6%
Died 4–5 years after transplant	1177	86.5%	5.9%	5.6%	0.0%	2.0%
Died ≥ 5 years after transplant	3299	81.3%	7.1%	9.9%	0.0%	1.7%
Kidney and pancreas						
Age ≥ 21 years	25 458	68.8%	5.9%	23.1%	1.3%	0.9%
Age < 21 years	401	76.8%	11.7%	9.7%	0.5%	1.2%
Non-K/P organs						
Age ≥ 21 years	17 642	88.7%	7.3%	3.3%	0.0%	0.7%
Age < 21 years	2060	84.6%	14.0%	0.7%	0.0%	0.6%

Source: SRTR data analyses, August 2002.

deaths that were identified by this source 'first', and will depend on the order chosen. Therefore, a small contribution from a secondary source (the CMS ESRD data, for example) does not mean that that source identifies few deaths; it may simply identify the same deaths as sources searched earlier.

Table 5 reports on transplant recipient deaths identified by any of the sources and occurring from 1991 through 1999. This range of years was chosen because 1999 was the last year for which the NDI was searched. For patients who have had more than one transplant, transplant date (for computing survival time) and organ are determined from the first transplant. Statistics for kidney and pancreas patients are reported separately from those receiving other organs because the data differ substantially for the two groups. These differences are due to the existence of an alternative treatment (dialysis) for kidney failure, differences in data collection (e.g. OPTN-based follow-up only for 2 years after graft failure), and the availability of alternative sources of information (CMS ESRD).

The OPTN data provided information on only 75% of the deaths for kidneys and pancreata (K/P) but 96% of deaths for all other organs. However, for deaths in the first year after transplant, the OPTN data cover 99% of the non-K/P deaths and 95% of the K/P deaths. This explains in part the result reported in the 'Analytical Approaches' article that, for many transplant programs, center-specific survival is diminished little, if not improved, when SSDMF data are considered. Thus for 1-year survival, the OPTN data are quite good for the nation as a whole, but the remaining sources are particularly important for longer follow-up times.

The contribution of the SSDMF increases steadily as the survival period increases. For non-K/P organs, the contribution of the SSDMF rises to 6% after 5 years. For K/P organs, the increase is much more rapid, rising to 13% for 1-2 years following transplant and exceeding 32% for 5 and more years. The rise in the SSDMF contribution as survival time increases suggests that the transplant centers lose contact with patients as the time since transplant increases, and the higher percentages for K/P organs suggest that this happens even more rapidly for K/P recipients. This difference presumably occurs because dialysis is available as a treatment after a kidney graft failure, while transplantation is the only definitive treatment available for the failure of most other organs. Thus kidney recipients may be more likely to move out of the transplantation system and are less likely to be followed by a transplant center.

As expected, the CMS ESRD data contributed no deaths to the organs other than kidney and pancreas. Even with kidney and pancreas, the incremental contribution of the CMS ESRD data is only 1%. The NDI makes an even smaller contribution of 0.8%, or 352 deaths out of

45561. It thus appears that the combination of the OPTN data and the SSDMF does a very good job of identifying deaths.

Table 5 also shows results for two age groups, divided at age 21. For both organ groups, secondary OPTN sources contribute almost twice as much in the younger group than in the older group. This may be because younger patients are better candidates for a retransplant after a graft failure and thus are more likely to be relisted and retransplanted. The SSDMF has a much larger contribution in the older group than in the younger, although the SSDMF still contributes 9.7% of the deaths among the younger kidney and pancreas recipients. This may be a combined effect of the SSA covering more of the older patients and the OPTN data sources covering more of the younger patients.

When examined in this order, the CMS ESRD and NDI sources each contribute less than 1% of the deaths: 336 CMS ESRD deaths and 352 NDI deaths out of a total of 45561. The largest contribution of the NDI for a subgroup is only 2%. We expected the NDI to make a larger contribution among younger patients on the assumption that the SSDMF would miss many younger patients, but the contribution in this group is minimal. It is not clear whether the other sources catch most of the deaths in this group or whether the NDI also is missing deaths among younger patients.

So far, we have shown that overall ascertainment of mortality looks good when all sources are considered. Next we address the question of whether all sources are necessary. Specifically, if we have good mortality data from secondary sources, how important is the OPTN membership as a data source for mortality?

Table 6 is similar to Table 5 but orders the death sources differently in order to show the deaths uniquely contributed by the OPTN data after deaths from the SSDMF and CMS ESRD data have been counted. When examined in this order, the OPTN data contribute 14% of the deaths. For kidney and pancreas, the OPTN data contribute only 5% for patients aged 21 and over, but they contribute 27% for patients under 21. For other organs, the OPTN data contribute 21% for the older group and 73% for the younger group. While these contributions decline with time, for deaths 5 or more years after transplant the percentages are still 17% for organs other than kidney and pancreas.

We conclude that at the national level, the OPTN data are very complete for 1-year survival, and that the SSDMF and CMS data are important for longer-term survival analyses, particularly for kidneys. Using the NDI is probably not worth the additional expense. While we do not know what proportion of actual deaths is missed by all these sources taken together, the fact that the two sources

Table 6: Distribution of deaths from 1991 to 1999 among transplant recipients by source of death date, time after first transplant, and patient age at death, with alternate ordering of sources to show unique contribution of OPTN data

	Deaths	Source of death date				
		SSDMF	CMS ESRD	Primary OPTN	Secondary OPTN	NDI
All	45 561	82.2%	2.8%	12.7%	1.5%	0.8%
Kidney and pancreas (K/P)	25 859	89.6%	4.8%	4.3%	0.4%	0.9%
Non-K/P organs	19 702	72.5%	0.2%	23.8%	2.9%	0.6%
Kidney and pancreas (K/P)						
Age ≥ 21 years	25 458	89.9%	4.8%	4.0%	0.4%	0.9%
Age < 21 years	401	71.1%	4.0%	20.7%	3.0%	1.2%
Non-K/P organs						
Age ≥ 21 years	17 642	77.8%	0.2%	19.2%	2.1%	0.7%
Age < 21 years	2060	26.7%	0.0%	62.8%	9.8%	0.6%
Kidney and pancreas (K/P)						
Died within 1 year of transplant	4504	89.8%	3.8%	5.6%	0.6%	0.2%
Died ≥ 5 years after transplant	12 081	88.7%	5.8%	4.0%	0.4%	1.1%
Non-K/P organs						
Died within 1 year of transplant	9651	67.9%	0.0%	28.3%	3.7%	0.1%
Died ≥ 5 years after transplant	3299	80.4%	0.6%	14.9%	2.3%	1.7%

Source: SRTR data analyses, August 2002.

added last contribute so few additional deaths suggests that a satisfactory fraction of deaths is found, and finally, because the SSDMF and OPTN each contribute a unique set of deaths, it is important to avoid relying on only one or the other.

The 'Analytical Approaches' article in the Annual Report discusses the use of the SSDMF in survival analyses. When deaths identified by the SSDMF are added to those identified by the OPTN data, we must also adjust the follow-up time for all patients. If information is only added about persons who die, then death rates will be overstated. The SRTR assumes that with the SSDMF data we know about virtually all of the deaths; a corollary of this approach is to assume that patients survive after transplant until the end of the study period during which we expect each source to capture deaths, unless we know otherwise. Therefore we do not censor patients at the last OPTN follow-up date, instead extending the follow-up time to the end of the study period. This adjustment results in almost no change in survival measures at the national level, even for 5- and 10-year survival. The lack of change even for these longer study periods—in which we have shown that many deaths are missing—suggests that the recipients actually followed by the transplant centers constitute an unbiased sample, and are similar to those patients who are lost to follow-up during the study period. However, at the transplant program level, some programs do show substantially different survival measures when the SSDMF data are added.

Other external sources and strategies

For measures other than mortality and graft failure, several additional data sources may also be incorporated with primary data sources for research on transplantation and

data validation. For example, the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute, one of the most complete sources of information on cancer incidence and survival in the United States, may be incorporated. After testing initial incorporation of SEER data from southeast Michigan, the SRTR hopes to make use of SEER's highly accurate cancer registries both for validating the post-transplant malignancy data reported on follow-up forms to the OPTN, and for gaining more complete information for time periods before the recent inception of malignancy ascertainment by the OPTN.

In some cases, data that are useful to correlate with each other are not collected by the OPTN at the same time. For example, in order to simulate the effects of the recent allocation rule change for livers from an urgency status-based one to MELD, it is necessary to have a period of data collection for which we know both the MELD score and the urgency status for each patient. There was a short period during which both measures were collected, but doing so was voluntary. Therefore, it has been useful to obtain hospital laboratory data for actual candidates on the waiting list, in order to associate an urgency status with a distribution of calculated MELDs. These data have also allowed an earlier look at associations between waiting list and post-transplant outcomes than might have been afforded by waiting for real allocation MELDs; they also allow a comparison of the associations between these outcomes and MELD to the former, more discrete, urgency status system. Going back to Figure 1, these data augment the candidate status history file.

Other external data sources do not necessarily require direct linking with primary source data in order to be

useful. For example, the OPTN, SRTR, and other researchers have investigated methods to make associations between OPO practice patterns and donor procurement, considering the suitability for transplantation of deaths in hospitals served by each OPO. The NCHS provides files that can help tabulate numbers of 'evaluable' deaths (deaths that provide a suitable source of organs, given cause, circumstance, and location of death), as well as demographic data about the deceased.

Finally, the OPTN and SRTR are together investigating the possibility of sampling strategies to maintain or expand the scope of data collection while also decreasing the burden of data collection on the facilities. It is possible that certain research may not require data to be collected regarding all transplant recipients, and perhaps a subset of patients would be selected for an extended follow-up form to cover these areas.

Conclusions

We believe that researchers interested in any aspect of transplantation, from donor recovery to organ allocation to post-transplant survival, will find this article useful. We have shown that a tremendous effort has been in making these data high-quality and well-organized for research at the SRTR, OPTN, and among other researchers. Further, we have shown that these efforts have paid off. For many research questions, the data submitted to the OPTN are complete and of high quality; for other questions, secondary sources are easily integrated to improve data quality or expand data scope. These resources taken together pro-

vide a rich and accurate source of information about the transplant process.

Even the extensive effort of the OPTN and SRTR staff at ensuring high-quality and well-organized data for research pales in comparison to the resources devoted to data submission on the part of staff at transplant centers and OPOs. These OPTN members understand that improving patients' lives is an incremental process, the benefits of which may be long in being realized, and which often begins with ensuring that the information is available upon which to reach sound scientific conclusions. None of this rich source of data would be possible without these tireless efforts.

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